National Institutes of Health

NIH HTML-Formatted Data Stream Implementation Guide for the Competing Award Process

Version 1.0

February 22, 2000



Prepared by:

Office of Policy for Extramural Research Administration Office of Extramural Research Office of the Director National Institutes of Health Bethesda, MD 20893-7750

TABLE OF CONTENTS

1	PURPOSE AND BUSINESS OVERVIEW	4
	.1 DOCUMENT PURPOSE	4
	.2 Version and Release	
	.3 Business Usage and Definition	
	.4 References	
	.5 TERMS AND ABBREVIATIONS	
	.6 Organization of Document	6
	.7 How to Use This Document	
	.8 RESPONDENT BURDEN	6
•	DATA OVERVIEW	-
2		
	.1 Information Flows	
	.2 Data Usage by Business Usage	
	.3 DATA/TRANSACTION SET MODEL WITH USAGE MATRIX	
	.4 APPLICATIONS AND PROFILES	
	2.4.1 Organizational Profile	
	2.4.2 Professional Profile	
	.5 GENERAL PROCESSING RULES	
	2.5.1 Entity Rules	
	2.5.2 Data Element Rules	
	.6 ASCII TEXT	23
3	DATA DICTIONARY IMPLEMENTATION GUIDELINES	24
	.1 APPLICATION ENTITY DATA ELEMENTS	26
	.1 APPLICATION ENTITY DATA ELEMENTS	
	.3 BUDGET ENTITY DATA ELEMENTS	
	.4 BUDGET_ITEM ENTITY DATA ELEMENTS	
	.5 BUDGET_LABOR ENTITY DATA ELEMENTS	
	.6 BUDGET_PERIOD ENTITY DATA ELEMENTS	
	.7 CONTACT_INFORMATION ENTITY DATA ELEMENTS	
	.8 EDUCATION ENTITY DATA ELEMENTS	
	.9 EXTERNAL_ATTACHMENT ENTITY DATA ELEMENTS	
	.10 HUMAN SUBJECT Entity Data Elements	
	.11 IACUC ENTITY DATA ELEMENTS	
	.12 ICR ENTITY DATA ELEMENTS	
	.13 INDIVIDUAL ENTITY DATA ELEMENTS	34
	.14 IRB Entity Data Elements	35
	.15 MATRIX Entity Data Elements	35
	.16 ORGANIZATION ENTITY DATA ELEMENTS	36
	.17 OTHER_SUPPORT ENTITY DATA ELEMENTS	
	.18 OTHER_SUPPORT_PERIOD ENTITY DATA ELEMENTS	37
	.19 PARAGRAPH ENTITY DATA ELEMENTS	38
	.20 PROJECT ENTITY DATA ELEMENTS	
	.21 RACE_ETHNICITY ENTITY DATA ELEMENTS	
	.22 SOLICITATION_ANNOUNCEMENT ENTITY DATA ELEMENTS	39
	.23 YES_NO_CONDITION ENTITY DATA ELEMENTS	40
4	HTML-FORMATTED DATA STREAM SYNTAX	41
	.1 Data Element Rules	
	.1 DATA ELEMENT RULES	
	4.2.1 Basic Rules	
	4.2.1 Basic Rules	
	NIH HTML-Stream Implementation Guide For the Competing Application	
	1.11111112 Sucain implementation Gaine For the Competing Application	2

4.2.3	Specifying Data Elements With Multiple Values	43
APPENDIX A	A4	5

1 Purpose and Business Overview

1.1 Document Purpose

The purpose of the "NIH HTML-Formatted Data Stream Implementation Guide for the Competing Award Process" is to provide standardized data requirements and content to all users interested in submitting competitive grant application data [1] to the National Institutes of Health (NIH) via Hypertext Markup Language (HTML) formatted data streams. Use of HTML-formatted data streams requires a data dictionary and a set of syntax rules. Both the grant application data dictionary [2] and syntax rules [3] are maintained and published by the Interagency Electronic Grants Committee (IAEGC).

This guide provides a detailed explanation of the grant application data dictionary and syntax rules including the identification of valid code tables. This will aid users in the successful encoding of grant application data from a proprietary format to an HTML-formatted data stream (called an HTML-stream within the scope of this guide).

Expected users of this implementation guide include NIH grantee organizations and third party vendors that conduct business with NIH on behalf of a grantee organization (i.e., grantee organization agents).

1.2 Version and Release

The IAEGC data dictionary for the grant application is based on the Accredited Standards Committee (ASC) X12 194 transaction set [4]; specifically, the X12 standards approved for publication in December of 1997, referred to as Version 4 Release 1 (004010).

1.3 Business Usage and Definition

NIH has deployed an HTML-stream pilot system to receive and validate competitive grant application data. Grantee organizations (or their agents) use the grant application data dictionary and encoding rules to format grant application data for transmission to this pilot system.

The NIH HTML-stream pilot system is being deployed as a phased implementation. Phase one, which is currently underway, accepts test data for the following sections of the grant application: face page, abstract, description of performance sites and key personnel, research plan specific aims, and the budget. Phase two, for which this manual is written, is an extension of phase one, supporting the entire competitive application.

The data dictionary used for phase two is syntactically different from the data dictionary used for phase one. User feedback has resulted in a restructuring of the entities (see section 3) and data elements comprising an HTML-stream. The new entity structure

should reduce the burden of generating HTML-streams. The new entity structure, however, is not backward compatible with phase one. This means that HTML-streams generated for phase one cannot be used with phase two.

Phase two of the NIH HTML-stream pilot has three constraints. First, as with phase one, only test data is accepted. Second, only competing continuations and revisions are supported (i.e., no supplements or new applications). Last, only single project research applications are supported. This means that applications for Research Career Awards, Research Training Grants, or Construction Grants, as well as applications with foreign components, subprojects, or consortium arrangements will not be accepted for phase two.

1.4 References

- 1. U.S. Department of Health and Human Services, "Application for a Public Health Service Grant (PHS 398)." Rev. 4/98. OMB No. 0925-0001. Form approved through 02/28/2001.
- 2. "Data Dictionary for the Grant Application." Interagency Electronic Grants Committee.
- 3. "Syntax Rules for HTML-Formatted Data Streams." Interagnecy Electronic Grants Committee
- 4. "ASC X12 194 Transaction Set. Federal Implementation Conventions." Version 004010. September, 1998.
- 5. "Table Extensions for the Common Gateway Interface." Buccigrossi, Robert. Turner Consulting Group. February 4, 1997.

1.5 Terms and Abbreviations

194	X12 Grant or Assistance Application
398	Application for a Public Health Service Grant
AO	Administrative Officer
ASC	Accredited Standards Committee
DUNS	Data Universal Numbering System
EIN	Entity Identification Number
GUIDe	Government User Identifier
HTML	Hypertext Markup Language
HTTP	Hypertext Transfer Protocol
IACUC	Institutional Animal Care and Use Committee
IAEGC	Interagency Electronic Grants Committee
IC	Implementation Convention
IPF	Institutional Profile
IRB	Institutional Review Board
NIH	National Institutes of Health
OS	Other Support

PHS Public Health Service
PI Principal Investigator
PPF Professional Profile
RFA Request for Application
SO Signing Official
SSN Social Security Number

1.6 Organization of Document

This document, the "NIH HTML-Formatted Data Stream Implementation Guide for the Competing Award Process", contains four major sections. Section 1 introduces the manual. Section 2 provides a data overview. Section 3 presents the grant application data dictionary as it applies to an NIH competitive grant application, and section 4 specifies the HTML-formatted data stream syntax. This document also contains one appendix. Appendix A provides a sample PHS 398 application and the corresponding HTML-stream.

1.7 How to Use This Document

This manual is written for the technical user who understands software programming terms and concepts. It can be used as a standalone document, because it reproduces both the relevant grant application data dictionary and syntax rules (from the IAEGC), as well as the relevant X12 194 code tables.

1.8 Respondent Burden

This information collection activity is linked to the *U.S. Department of Health and Human Services, Public Health Service, Grant Application (PHS 398, Rev. 4/98).* The PHS 398 form is approved through 02/28/2001; OMB No. 0925-0001.

The Public Health Service (PHS) estimates that it will take approximately 35 hours to complete this application for a regular research project grant. This estimate does not include time for development of the scientific plan. Items such as human subjects and vertebrate animals are cleared and accounted for separately, and are therefore also not part of the time estimate. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a current valid OMB control number. If you have any comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, send comments to: NIH, Project Clearance office, 6701 Rockledge Drive, MSC 7730, Bethesda, MD 20893-7730, ATTN: PRA (0925-0001). Do not send applications to this address.

2 Data Overview

2.1 Information Flows

The transmission of competitive grant application data from the grantee community to NIH takes place as shown:

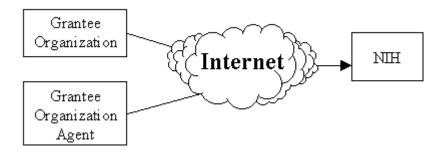


Figure 2.1. Data Stream Information Flow

2.2 Data Usage by Business Usage

The grant application data dictionary is categorized into *entities*. An entity is a collection of related data elements. For example, all data elements relevant to a person are specified in the INDIVIDUAL entity. The reader is advised to view these entities as tables in a relational database. This means that grantee organizations must map data from their grant application databases to the corresponding grant application entities and data elements.

The grant application data dictionary comprises 23 distinct entities. The hierarchical structure of these entities is depicted in the following diagram. Indentation is used to delineate ranks in the hierarchy.

Some entity names are followed by parenthesized values. These values are the codes permitted for instances of that particular entity. For example, the INDIVIDUAL entity under the PROJECT entity is followed by the codes 9P and 9K. An individual of type 9P is the project's principal investigator. An individual of type 9K is a key person on the project. In contrast, the INDIVIDUAL entity under the APPLICATION entity is followed by the codes AD and B. An individual of type AO is the administrative official, while an individual of type B is the official signing for the applicant organization.

The definitions for these alphanumeric codes are provided in section 3, within the relevant entity specifications.

APPLICATION contains PROJECT contains ORGANIZATION (61) contains CONTACT_INFORMATION contains INDIVIDUAL (9P, 9K) contains ORGANIZATION (9P, 9K) contains CONTACT INFORMATION contains EDUCATION contains PARAGRAPH (D, D.1, D.2, D.3, D.4, D.5, D.5.1) contains OTHER SUPPORT contains OTHER_SUPPORT_PERIOD contains ORGANIZATION (92) contains INDIVIDUAL (9P) contains RACE ETHNICITY contains PARAGRAPH (A, B.2, C.2, C.3, E.4, F.2, I.6) contains ANIMAL SUBJECT contains IACUC contains HUMAN_SUBJECT contains IRB contains MATRIX contains BUDGET contains BUDGET PERIOD contains BUDGET ITEM contains BUDGET LABOR contains INDIVIDUAL (9P, 9K) contains PARAGRAPH (C.1) contains ORGANIZATION (BY, SE) contains CONTACT_INFORMATION contains ICR contains PARAGRAPH (E.7)

Figure 2-2. Hierarchical Entity Structure

contains YES_NO_CONDITION (H0, H4, H5, H6, H7, H8, H9, I7, I8, J.1)

contains INDIVIDUAL (AD, 1B, AZ)

contains EXTERNAL ATTACHMENT

contains CONTACT INFORMATION

contains SOLICITATION ANNOUNCEMENT

2.3 Data/Transaction Set Model with Usage Matrix

The following matrix identifies the PHS 398 items supported in the NIH HTML-stream pilot. The matrix correlates 398 items with relevant entities, data elements and data codes. The data codes, which are taken from the X12 194 transaction set, are specified in parentheses.

The entity column in the usage matrix traces the complete hierarchical path beginning with the APPLICATION entity. For example, the ORGANIZATION entity is subordinate to several other entities. To properly identify the organization that is the source of other support for a researcher, the entity column specifies the path:

APPLICATION/PROJECT/INDIVIDUAL/OTHER_SUPPORT/ORGANIZATION.

Page	398 Item	Item Definition	Entity	Data Element
AA.1	Title of Project	Application Title	Application	Title
AA.2	RFA Number	Request For Application	Application/	Number
		Number	Solicitation_	
			Announcement	
AA.2	RFA Title	Request For Application Title	Application/	Title
			Solicitation_	
			Announcement	
AA.3	New Investigator	New investigator	Application/	Type (J.1)
			Yes_No_Condition	Response
AA.3a	Principal Investigator (PI)	Identify as PI	Application/Project/	Type (9P)
		PI Last name	Individual	Last_Name
		PI First name		First_Name
		PI Middle name		Middle_Name
		PI Name prefix		Prefix
		PI Name suffix		Suffix
		PI Government user ID		GUIDe
AA.3b	PI Degrees	PI degree	Application/Project/	Туре
	_	PI degree date	Individual/Education	Date
		PI major		Major
		PI area of specialization		Specialization
		Institution name		Institution
AA.3c	PI Social Security No	PI SSN	See page KK	See page KK
AA.3d	PI Position Title	PI position title	Application/Project/	Title
			Individual	
AA.3e	PI Mailing Address	PI street address	Application/Project/	Street_Address
		PI city	Individual/	City
		PI state	Contact_Information	State
		PI zip code		Zip_Code
		PI country code		Country
		PI county		County
		PI email address		Email_Address
		PI mail stop		Mail_Stop
AA.3f	PI Department	PI department	Application/Project/	Department
			Individual/	
			Organization	
AA.3g	PI Major Subdivision	PI major subdivision	Application/Project/	Division
			Individual/	
			Organization	
AA.3h	PI Telephone and Fax	PI telephone number	Application/Project/	Telephone_Number
		PI facsimile number	Individual/	Fax_Number
			Contact_Information	
AA.4	Human Subjects	Exemption number	Application/Project/	Exemption_Number
		Assurance of compliance #	Human_Subject/IRB	Assurance_Number
		IRB review pending		Approval_Pending
		IRB review type		Review_Type
		(full or expedited)		(Full vs. Expedited)
		IRB approval date		Approval_Date

Page	398 Item	Item Definition	Entity	Data Element
AA.5	Vertebrate Animals	Animal welfare assurance #	Application/Project/	Assurance_Number
		IACUC review pending	Animal_Subject/	Approval_Pending
		IACUC approval date	IACUC	Approval_Date
AA.6	Proposed Period of Support	Estimated start date	Application/Project	Start_Date
	– From			
AA.6	Proposed Period of Support	Estimated end date	Application/Project	End_Date
	– Through			
AA.6	Proposed Period of Support	Duration of project (in months)	Application/Project	Duration
AA.7	Costs Requested for Initial	Identify as initial budget period	Application/Project/	Period_Id (1)
	Budget Period		Budget/	
			Budget_Period	
AA.7	Costs Requested for Initial	Identify as direct costs	Application/Project/	Code (84)
	Budget Period	Direct costs	Budget/	Cost
		Identify as total costs	Budget_Period/	Code (38)
		Total Costs	Budget_Item	Cost
AA.8	Costs Requested Proposed	Identify as total budget	Application/Project/	Period_Id (T)
	Period of Support		Budget/	
			Budget_Period	
AA.8	Costs Requested for	Identify as direct costs	Application/Project/	Code (84)
	Proposed Period of Support	Direct costs	Budget/	Cost
		Identify as total costs	Budget_Period/	Code (38)
		Total Costs	Budget_Item	Cost
AA.9	Applicant Organization	Identify as applicant org.	Application/	Type (SE)
	Name	Organization IPF code	Organization	Profile_Id
		Organization name		Name
AA.9	Applicant Organization	Organization street address	Application/	Street_Address
	Address	Organization city	Organization/	City
		Organization state	Contact_Information	State
		Organization zip code		Zip_Code
		Organization country code		Country
AA.10	Type of Organization	Organization county Type of Organization	Application/	County Entity Type
AA.10	Type of Organization	Type of Organization Public – Federal	Application/	Entity_Type
		Public – Federal Public – State	Organization	(2R) (2F)
		Public – State Public – Local		(C6)
		Private Nonprofit		(A8)
		For Profit – General		(B9)
		For Profit – Small Business		(21)
AA.11	Organizational Component	Organizational component code	N/A	N/A
AA.11	Code	Olganizational component code	11/71	11/11
AA.12	Entity Identification	EIN	Application/	EIN
	Number	DUNS	Organization	DUNS
				District
	Nullioei	Congressional district	Organization	Congressional_

Page	398 Item	Item Definition	Entity	Data Element
A.13	Name of Administrative	Identify as AO	Application/	Type (AD)
	Official (AO)	AO last name	Individual	Last_Name
		AO first name		First_Name
		AO middle name		Middle_Name
		AO name prefix		Prefix
		AO name suffix		Suffix
		AO government user id		GUIDe
	AO Title	AO title		Title
A.13	AO Address	AO street address	Application/	Street_Address
		AO city	Individual/	City
		AO state	Contact_Information	State
		AO zip code	_	Zip_Code
		AO country code		Country
		AO county		County
		AO email address		Email_Address
		AO telephone number		Telephone_Number
		AO facsimile number		Fax_Number
		AO mail stop		Mail_Stop
A.14	Name of Signing Official	Identify as SO	Application/	Type (1B)
	(SO)	SO last name	Individual	Last_Name
		SO first name		First_Name
		SO middle name		Middle_Name
		SO name prefix		Prefix
		SO name suffix		Suffix
		SO government user id		GUIDe
	SO Title	SO title		Title
A.14	SO Address	SO street address	Application/	Street_Address
		SO city	Individual/	City
		SO state	Contact_Information	State
		SO zip code		Zip_Code
		SO country code		Country
		SO county		County
		SO email address		Email_Address
		SO telephone number		Telephone_Number
		SO facsimile number		Fax_Number
		SO mail stop		Mail_Stop
AA.15	PI Assurance	PI signature and date	N/A	N/A
AA.16	Applicant Org Certification	Application date	Application	Submission_Date
	and Acceptance			
BB	Abstract	Abstract text	Application/Project/	Type (A)
			Paragraph	Text
BB	Performance Site(s)	Identify a performance site	Application/Project/	Type (61)
		Organization name	Organization	Name
BB	Performance Site(s) Address	Organization city	Application/Project/	City
		Organization state	Organization/	State
		Organization country	Contact_Information	Country

Page	398 Item	Item Definition	Entity	Data Element
BB	Key Personnel	Key Personnel	Application/Project/	Type (9P,9K)
		Last name	Individual	Last_Name
		First name		First_Name
		Middle Name		Middle_Name
		Name prefix		Prefix
		Name suffix		Suffix
		Government User ID		GUIDe
BB	Key Personnel	Organization name	Application/Project/	Type (9P,9K)
		Organization DUNS	Individual/	Name
			Organization	DUNS
BB	Key Personnel	Role on project	Application/Project/	Project_Role
			Budget/	
			Budget_Period/	
			Budget_Labor	
DD	Initial Budget Period	Detailed budget for initial	Application/Project/	Period_Id (1)
		budget period	Budget/	_
			Budget_Period	
DD	From	Budget period start date	Application/Project/	Start_Date
			Budget/	_
			Budget_Period	
DD	Through	Budget period length	Application/Project/	Length
			Budget/	
			Budget_Period	
DD	Name	Last name	Application/Project/	Last_Name
		First name	Budget/	First_Name
		Middle name	Budget_Period/	Middle_Name
		Prefix	Budget_Labor/	Prefix
		Suffix	Individual	Suffix
DD	GUIDe	Government User ID of person	Application/Project/	GUIDe
			Budget/	
			Budget_Period/	
			Budget_Labor	
DD	Role on Project	Role on project	Application/Project/	Project_Role
			Budget/	
			Budget_Period/	
			Budget_Labor	
DD	Type Appt	Number of appointment	Application/Project/	Level_Effort_
		Months	Budget/	Months
			Budget_Period/	
			Budget_Labor	
DD	% Effort on Project	Level of effort as a percent	Application/Project/	Level_Effort_
			Budget/	Percentage
			Budget_Period/	
			Budget_Labor	
DD	Inst. Base Salary	Institutional base salary	Application/Project/	Salary
			Budget/	
			Budget_Period/	
			Budget_Labor	

Page	398 Item	Item Definition	Entity	Data Element
DD	Salary Requested	Dollar amount for requested salary	Application/Project/ Budget/ Budget_Period/ Budget_Item	Code (01) Cost
DD	Fringe Benefits	Dollar amount for fringe benefits	Application/Project/ Budget/ Budget_Period/ Budget_Item	Code (49) Cost
DD	Totals	N/A (NIH will calculate)	N/A	N/A
DD	Subtotals (NIH will calculate subtotals if not specified in application)	Total salaries requested Total fringe benefits	Application/Project/ Budget/ Budget_Period/ Budget_Item	Code (70) Cost Code (48) Cost
DD	[any budget item description]	Further description for any budgeted item	Application/Project/ Budget/ Budget_Period/ Budget_Item	Description
DD	Consultant Costs	Consultant costs	Application/Project/ Budget/ Budget_Period/ Budget_Item	Code (81) Cost
DD	Equipment	Equipment costs – itemized	Application/Project/ Budget/ Budget_Period/ Budget_Item	Code (42) Cost
DD	Supplies	Cost of supplies	Application/Project/ Budget/ Budget_Period/ Budget_Item	Code (43) Cost
DD	Travel	Domestic and foreign travel costs	Application/Project/ Budget/ Budget_Period/ Budget_Item	Code (52) Cost
DD	Inpatient	Inpatient patient care costs	Application/Project/ Budget/ Budget_Period/ Budget_Item	Code (85) Cost
DD	Outpatient	Outpatient patient care costs	Application/Project/ Budget/ Budget_Period/ Budget_Item	Code (BL) Cost
DD	Alterations and Renovations	Cost of alterations and renovations	Application/Project/ Budget/ Budget_Period/ Budget_Item	Code (87) Cost

Page	398 Item	Item Definition	Entity	Data Element
DD	Other Expenses	Other itemized direct costs	Application/Project/	Cost
		Ancillary service contracts	Budget/	Code (46)
		Equipment maintenance	Budget_Period/	Code (EH)
		Publication Costs	Budget_Item	Code (80)
		ADP services		Code (82)
		Animal Costs		Code (86)
		Rent/Lease of equip/facilities		Code (RL)
		Other		Code (39)
DD	Subtotal Direct Costs	N/A (NIH will calculate)	N/A	N/A
DD	Consortium/Contractual	Consortium/Contractual costs	N/A	N/A
	Costs	are not supported in this release		
DD	Total Direct Costs	Same as AA.7	N/A	N/A
EE	Additional Years of Support	For each year (2,3,4,5) of	Application/Project/	Period_Id (2,3,4,5)
	Requested	additional support	Budget/	
			Budget_Period	
EE	Personnel	Salary and fringe benefits	Application/Project/	Code (71)
			Budget/	Cost
			Budget_Period/	
			Budget_Item	
EE	Consultant Costs	Consultant costs	Application/Project/	Code (81)
			Budget/	Cost
			Budget_Period/	
			Budget_Item	
EE	Equipment	Equipment costs – total	Application/Project/	Code (72)
			Budget/	Cost
			Budget_Period/	
			Budget_Item	
EE	Supplies	Cost of supplies	Application/Project/	Code (43)
			Budget/	Cost
			Budget_Period/	
EE	T. 1	G . G . 1	Budget_Item	G 1 (52)
EE	Travel	Cost of travel	Application/Project/	Code (52)
			Budget/	Cost
			Budget_Period/	
PP	Tonotions	Innation and instruction	Budget_Item	Cada (95)
EE	Inpatient	Inpatient patient care costs	Application/Project/	Code (85)
			Budget/	Cost
			Budget_Period/	
PP	Outnotiont	Outpotiont motiont	Budget_Item Application/Project/	Codo (DL)
EE	Outpatient	Outpatient patient care costs	Application/Project/	Code (BL)
			Budget/	Cost
			Budget_Period/ Budget_Item	
EE	Alterations and Renovations	Cost of alterations and	_	Code (97)
EE	Anterations and Kenovations		Application/Project/	Code (87)
		renovations	Budget/	Cost
			Budget_Period/	
			Budget_Item	1

Page	398 Item	Item Definition	Entity	Data Element
EE	Other Expenses	Costs for any other expenses	Application/Project/	Code (39)
			Budget/	Cost
			Budget_Period/	
			Budget_Item	
EE	N/A	Other costs itemized for 194	Application/Project/	Cost
		Ancillary service contracts	Budget/	Code (46)
		Equipment maintenance	Budget_Period/	Code (EH)
		Publication Costs	Budget_Item	Code (80)
		ADP services		Code (82)
		Animal Costs Rent/Lease of equip/facilities		Code (86) Code (RL)
EE	Total Direct Costs	Same as AA.8	N/A	N/A
EE	Justification	Budget justification	Application/Project/	Type (C.1)
EE	Justification	Budget Justification	Budget/Paragraph	Text
FF	Biographical Sketch - Name	PI or key person	Application/Project/	Type (9P or 9K)
**	Biographical Sketch Tvame	Last name	Individual	Last_Name
		First name	1101/10001	First Name
		Middle Name		Middle Name
		Name prefix		Prefix
		Name suffix		Suffix
		Government User ID		GUIDe
FF	Position Title	Position title	Application/Project/	Title
			Individual	
FF	Education/Training	Degree	Application/Project/	Type
		Year	Individual/Education	Date
		Field of study		Major
		Area of specialization		Specialization
FF	D 1 1D 6 1 1	Institution name	A 1' ' /D ' //	Institution
FF	Research and Professional	Research and professional	Application/Project/	Text
	Experience	Experience	Individual/Paragraph	Type (D)
		Previous employment Experience		Type (D.2) Type (D.1)
		Honors		Type (D.1) Type (D.3)
		Memberships		Type (D.4)
		Publications		Type (D.5, D.5.1)
GG	Other Support (OS)	Active Other Support	Application/Project/	Type (37)
	Status	Pending Other Support	Individual/	Type (37)
			Other_Support	71 \ -/
GG	Project Dates	OS project start date	Application/Project/	Start_Date
			Individual/	
		OS project end date	Other_Support/	End_Date
			Other_Support_Period	
GG	Annual Direct Costs	Annual direct costs	Application/Project/	Annual_Cost
			Individual/	
			Other_Support	
GG	Percent Effort	Percent effort	Application/Project/	Level_Effort_
			Individual/	Percentage
			Other_Support/	
			Other_Support_Period	

Active Support Project Project number Application/Project/ Individual/ Other Support Title Application/Project/ Individual/ Other Support	Page	398 Item	Item Definition	Entity	Data Element
Project title	GG		Project number		Award_Number
Pending Support Project Information		Information			
Information					
Project title	GG		Project number		
GG Source Source Source Application/Project/ Individual/ Other_Support/ Organization GG Major Goals Major goals Application/Project/ Individual/ Other_Support Organization GG Overlap Overlap Application/Project/ Individual/ Other_Support		Information	Donie od didle		
Individual/ Other_Support/ Organization Name	CC	G			
GG Major Goals Major goals Major goals Major goals Major goals Application/Project/ Individual/ Other Support Application/Project/ Individual/ Other Support Application/Project/ Individual/ Other Support GG Overlap GF Principal Investigator GF Principal	GG	Source	Source		
GG Major Goals Major goals Application/Project/ Individual/ Other_Support Application/Project/ Individual/ Other_Support Application/Project/ Individual/ Other_Support Application/Project/ Individual/ Other_Support Os PI first name Os PI first name Os PI first name Os PI first name Other facilities Application/Project/ Individual Individual Individual Individual Application Interest Individual Application Interest Individual Application Interest Individual Ind					Ivanic
GG					
GG Overlap Overlap Application/Project/ Individual/ Other_Support Individual/ Other_Support/ Individual Other_Support/ Individual Other_Support/ Individual Other_Support/ Individual Other_Support/ Individual Application/Project/ Paragraph Text HH Major Equipment Major equipment Application/Project/ Paragraph Text II Type of Application Revision Revision of application number Revision of application number Other_Support Other_Suppo	GG	Maior Goals	Major goals		Major Goals
GG Overlap Overlap Application/Project/ Individual/ Other_Support OS PI last name OS PI first name OS PI fir			The grants	11	
GG Overlap Overlap Application/Project/ Individual/ Other_Support Individual/ Other_Support Other_Support Individual Other_Support Individual Other_Support Individual Other_Support Individual Other_Support Individual Application/Project/ Individual Application/Project/ Other_Support Individual Application/Project/ Paragraph Text HH Major Equipment Major equipment Application/Project/ Paragraph Text II Type of Application Revision Revision of application number Other Appl_Number_of_Orig_Sub Other_Supported Individual Inventions and Patents Identify as inventions/patents Identify as previously reported Identify as previously reported Identify as former PI Last name First name Middle name Name prefix Name suffix Government User ID II Foreign Application Application MyA N/A II Foreign Application Application N/A N/A				Other_Support	
GG Principal Investigator OS PI last name OS PI first name OS PI Individual OI paragraph OS PI Individual OI paragraph OS PI Individual OI paragraph OI paragr	GG	Overlap	Overlap		Overlap
Application/Project/ Individual/ Other_Support/ Individual/ Other_Support/ Individual Prist_Name Application/Project/ Individual				Individual/	
OS PI first name Individual					
HH Facilities Describe laboratory, clinical, animal, computer, office, and other facilities HH Major Equipment Major equipment Application/Project/ Paragraph II Type of Application Revision Revision of application number II Type of Application Competing continuation Continuation of grant number II Inventions and Patents Identify as inventions/patents Identify as previously reported II Change of PI Identify as former PI Last name First name Middle name Name prefix Name suffix Government User ID II Foreign Application Application Project/ Prefix Government User ID II Foreign Application Application Project/ Prefix Suffix Government User ID II Foreign Application Application Project/ Prefix Suffix Government User ID II Foreign Application Application Project/ Prefix Suffix Government User ID II Foreign Application Application Project/ Prefix Suffix Government User ID II Foreign Application Application Project/ Prefix Suffix Government User ID II Foreign Application Application Project/ Prefix Suffix Government User ID II Foreign Application Project/ Paragraph Text Type (C.2) Type (C.2) Text Type (C.3) Text Type (GC) Application Application Application/Project/ Paragraph Type (GC) Application Type (6C) Application/Project/ Paragraph Type (GC) Application Type (AC) Application Application Application Application Type (AC) Application Type (AC) Application Application Type (AC) Application	GG	Principal Investigator			
Individual Application/Project/ Paragraph Text			OS PI first name		_
HH Facilities Describe laboratory, clinical, animal, computer, office, and other facilities HH Major Equipment Major equipment Application/Project/ Paragraph Text II Type of Application Revision Revision of application number Orig_Sub II Type of Application Competing continuation Continuation of grant number Identify as inventions/patents Identify as previously reported II Change of PI Identify as former PI Last name First name Middle name Name prefix Name suffix Government User IID II Foreign Application Application Application Widal components are not supported Paragraph Paragraph Paragraph Prefix Type (C.2) Type (C.2) Text Type (C.2) Type (C.2) Text Type (C.3) Type (6R) Application Project/ Orig_Sub Application Type (6C) Award_Id Type (I.6) Text (Reported, Not Reported) Type (AZ) Last Name First_Name Middle_Name Prefix Suffix GOUIDE N/A					First_Name
animal, computer, office, and other facilities HH Major Equipment Major equipment Application/Project/ Paragraph Text II Type of Application Revision Revision of application number II Type of Application Competing continuation Continuation of grant number Application Type (6C) II Inventions and Patents Identify as inventions/patents Identify as previously reported In It Change of PI Identify as former PI Last name First name Middle name Name prefix Name suffix Government User ID II Foreign Application Application Paragraph Text Major equipment Application/Project/ Type (C.3) Type (C.3) Type (C.3) Type (GR) Appl_Number_of_Orig_Sub Application Type (6C) Type (6C) Appl_Number_of_Orig_Sub Application/Project/ Type (I.6) Text (Reported, Not Reported) Type (I.6) Text (Reported, Not Reported) Type (AZ) Last_Name Middle_name Middle_Name Prefix Suffix Government User ID II Foreign Application Applications with foreign components are not supported					
Other facilities HH Major Equipment Major equipment Application/Project/ Paragraph Text	HH	Facilities			
HH Major Equipment Major equipment Application/Project/ Paragraph Text II Type of Application Revision Revision of application number II Type of Application Competing continuation Continuation of grant number II Inventions and Patents Identify as inventions/patents Identify as previously reported II Change of PI Identify as former PI Last name First name Middle name Name prefix Name suffix Government User ID II Foreign Application Application Major equipment Application/Project/ Application Type (6R) Application Type (6C) Award_Id Application/Project/ Paragraph Text (Reported, Not Reported) Type (1.6) Text (Reported, Not Reported) Application/Project/ Paragraph Text (Reported, Not Reported) Type (AZ) Last_Name First_Name Middle_Name Prefix Suffix Government User ID II Foreign Application Applications with foreign components are not supported				Paragrapn	Text
Text II Type of Application Revision Revision Application Application Type (6R) Appl_Number_of_Orig_Sub	НН	Major Equipment		Application/Project/	Type (C 3)
II	1111	Wajor Equipment	Wagor equipment		
Revision of application number Repl_Number_of_Orig_Sub Application Type (6C) Award_Id Application/Project/ Paragraph Text (Reported, Not Reported) Reported) Reported Reported Reported Reported Reported Reported Reported Identify as former PI Last name First name Middle name Name prefix Name suffix Government User ID II Foreign Application Applications with foreign components are not supported Reported N/A N/A	II	Type of Application	Revision		
II Type of Application Competing continuation Continuation Continuation of grant number II Inventions and Patents Identify as inventions/patents Identify as previously reported II Change of PI Identify as former PI Last name First name Middle name Name prefix Name suffix Government User ID II Foreign Application Application Continuation (Continuation of grant number (Continuation of grant num					* *
Continuation of grant number II Inventions and Patents Identify as inventions/patents Identify as previously reported II Change of PI II Change of PI II Change of PI II Change of PI III Foreign Application					
II Inventions and Patents Identify as inventions/patents Identify as previously reported Inventions and Patents Identify as previously reported Identify as previously reported Identify as previously reported Identify as former PI Identify as	II	Type of Application	Competing continuation	Application	Type (6C)
Identify as previously reported Paragraph Text (Reported, Not Reported) II Change of PI Identify as former PI Application/Individual Last_Name First name Middle name Name prefix Name suffix Government User ID II Foreign Application Application Applications with foreign components are not supported Paragraph Text (Reported, Not Reported) Total Carlot Reported, Not Reported					Award_Id
II Change of PI Identify as former PI Last name First name Middle name Name prefix Name suffix Government User ID II Foreign Application Application Reported Reported) Application/Individual Type (AZ) Last_Name First_Name Middle_Name Prist_Name Middle_Name Prefix Suffix GUIDe Name suffix GuIDe N/A N/A	II	Inventions and Patents			
II Change of PI Identify as former PI Last name First name Middle name Name prefix Name suffix Government User ID II Foreign Application Application Supported II Foreign Application Identify as former PI Last_Name First_Name Middle_Name Prefix Suffix GUIDe N/A N/A			Identify as previously reported	Paragraph	
Last name First name Middle name Name prefix Name suffix Government User ID II Foreign Application Applications with foreign components are not supported Last_Name First_Name Middle_Name Prefix Suffix GUIDe N/A N/A					
First name Middle name Name prefix Name suffix Government User ID II Foreign Application Applications with foreign components are not supported First_Name Middle_Name Prefix Suffix GUIDe N/A N/A	II	Change of PI		Application/Individual	
Middle name Name prefix Name suffix Government User ID II Foreign Application Applications with foreign components are not supported Middle_Name Prefix Suffix GUIDe N/A N/A					
Name prefix Name suffix Suffix Government User ID II Foreign Application Applications with foreign components are not supported N/A N/A					
Name suffix Government User ID II Foreign Application Applications with foreign components are not supported N/A Suffix GUIDe N/A N/A					
Government User ID II Foreign Application Applications with foreign components are not supported GUIDe N/A N/A					
II Foreign Application Applications with foreign N/A N/A components are not supported					
components are not supported	Ш	Foreign Application		N/A	
in this release			in this release		

Page	398 Item	Item Definition	Entity	Data Element
II	Assurances/Certifications	Human Subjects	See IRB	N/A
		Vertebrate Animals	See IACUC	N/A
		Debarment and Suspension	Application/	Type (I8)
		Drug-Free Workplace	Yes_No_Condition	Type (H5)
		Lobbying		Type (H0, H4)
		Delinquent Federal Debt		Type (I7)
		Research Misconduct		Type (H6)
		Discrimination Regulations		Type (H8)
		Financial Conflict of Interest		Type (H9)
		Response to condition		Response
TT	D	Explanatory text	A 1' /D ' //	Description
II	Program Income	Budget period, anticipated	Application/Project/	Type (E.4)
		amount, source(s) (all provided	Paragraph	Text
II	Indinact Costs	in one text field)	Amplication/	Agraga Data
111	Indirect Costs	Agreement date DHHS Regional Office or	Application/	Agree_Date Filing_Location
		PHS Cost Advisory Office	Organization/ICR	rining_Location
II	Calculation	Identify as indirect costs	Application/Project/	Code (09)
111	Calculation	Amount of base	Budget/	Quantity
		Rate applied	Budget_Period/	Percentage_Rate
		Indirect Costs	Budget_Item	Cost
II	Check Appropriate Boxes	Salary and wages base	Application/Project/	Code (51)
		Modified total direct cost base	Budget/	Code (47)
		Off-site, other special rate, or	Budget_Period/	Code (ZZ)
		more than one rate involved	Budget_Item	,
		Other base	0 -	Code (08)
II	Explanation	Identify as indirect cost text	Application/	Type (E.7)
		Explanation for indirect costs	Organization/ICR/	Text
			Paragraph	
II	Smoke-Free Workplace	Smoke-free workplace	Application/	Type (H7)
		Response to condition	Yes_No_Condition	Response
		Explanatory text		Description
JJ	Personnel Report – Name	Identify as PI	Application/Project/	Type (9P)
		Identify as key person	Budget/	Type (9K)
		Last name	Budget_Period/	Last_Name
		First name	Budget_Labor/	First_Name
		Middle name	Individual	Middle_Name
		Prefix Suffix		Prefix Suffix
		Government user ID		GUIDe
JJ	Degrees	NIH has the degree information	N/A	N/A
33	Degrees	from the previous application.	11/11	11/11
JJ	SSN	Social Security Number	Application/Project/	SSN
		1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1	Budget/	
			Budget_Period/	
			Budget_Labor/	
			Individual	
JJ	Role on Project	NIH has the project role from	N/A	N/A
		the previous application.		
L	1	p. c. total application	l .	,L

Page	398 Item	Item Definition	Entity	Data Element
JJ	Date of Birth	Date of birth	Application/Project/ Budget/ Budget_Period/ Budget_Labor/ Individual	Birth_Date
JJ	Annual % Effort	Annual percent effort	Application/Project/ Budget/ Budget_Period/ Budget_Labor	Previous_Level_ Effort_Percentage
KK	PI Social Security No	PI SSN	Application/Project/ Individual	SSN
KK	Date of Birth	PI date of birth	Application/Project/ Individual	Birth_Date
KK	Gender	PI gender	Application/Project/ Individual	Sex
KK	Race and/or Ethnic Origin	PI race and/or ethnic origin	Application/Project/ Individual/ Race_Ethnicity	Туре
N/A	N/A	Identification of Federal agency Cite DUNS Number Use value of 927645168	Application/ Organization	Type (BY) DUNS
N/A	N/A	How research plan is submitted: As paper mailed to NIH As NIH file upload As X12 transaction set Identify as X12 102 Unique id for X12 102 transaction	Application/ External_Attachment	Type (SD) Transmission_Type (BM) (DA) (EL) Transaction_Set_Id Transaction_ Number
N/A	N/A	Matrix start Matrix end Number of subjects Title of study	Application/Project/ Human_Subject/ Matrix	Start_Cell End_Cell Data Title
N/A	N/A	Research plan specific aims	Application/Project/ Paragraph	Type (B.2) Text
N/A	N/A	Cover letter	Application/Project/ Paragraph	Type (F.2) Text

2.4 Applications and Profiles

Grantee organizations and users must register with NIH before being referenced on an application. Once registered, the grantee organization maintains its Organizational Profile (OPF) and each user maintains a Professional Profile (PPF). When submitting grant application data to NIH via an HTML-stream, there are business rules that govern how information in the application affects the profiles. In general, grant application data elements:

- must match the registered profile values, or
- are stored as part of the application, but do not change the profile, or
- change the profile.

The specific business rules are described below. Note that not all the data elements listed are required to be present on an application.

2.4.1 Organizational Profile

With respect to the applicant organization, no organizational data submitted via the HTML-stream affects the OPF. The following grant application data elements *must* match OPF values registered with NIH. If not, the transaction is rejected.

- Institutional Profile (IPF) code
- DUNS number
- EIN

The following grant application data elements *should* match OPF values registered with NIH. If not, the transaction is accepted, but the dissimilar data elements are ignored, and an email message is returned to the grantee identifying the inconsistency(ies).

- organization name
- organization type
- congressional district
- department (for the PI)
- school or major subdivision (for the PI)

The following data elements are stored as part of the application, but do not change the OPF.

- address (street address, city, state, etc.)
- assurance and certification data

2.4.2 Professional Profile

NIH uses a Unique Person Algorithm (based on various PPF data elements) to uniquely identify key individuals on a grant application. If the algorithm *fails* (i.e., cannot uniquely identify an individual), the transaction is rejected. Note that failure to recognize even one key person causes the grant application to be rejected. If the algorithm succeeds (i.e., uniquely identifies an individual), PPF data elements are handled as follows.

The following grant application data elements *must* match PPF values registered with NIH. If not, the transaction is rejected.

- Government User Identifier (GUIDe)
- Social Security Number (SSN) note that an invalid GUIDe or SSN will result in the algorithm failing. They are listed here only for completeness.

The following grant application data elements *should* match PPF values registered with NIH. If not, they are stored as part of the application (they do not change the PPF), but an email message is returned to the grantee identifying the inconsistency(ies).

- name
- date of birth
- gender
- race/ethnicity

The following data elements are stored as part of the application, but do not change the user's PPF.

- position title
- address (street address, city, state, etc.)
- contact data (phone, fax, email)
- degree (i.e., education)
- research and professional experience

Publications are handled as follows. Each publication specified in the grant application is compared to the PPF registered with NIH. If a match is found, the publication is stored as part of the application. If a match is not found,

- the publication is stored as part of the application
- the publication is added to the individual's PPF
- an email message is returned to the grantee identifying the PPF update.

2.5 General Processing Rules

NIH applies some general rules when processing data streams. Presently, the rules are used to ensure conformance to this guide. This means that the rules are specific to NIH, and that data streams will be rejected if non-conforming. Future versions of these processing rules might relax some of the constraints in the interest of supporting grantees who use HTML-streams to submit data to multiple agency systems.

The NIH processing rules for HTML-streams containing competing grant applications can be divided into *Entity Rules* and *Data Element Rules*.

2.5.1 Entity Rules

- 1. If a data stream contains an entity that is not recognized, the data stream is rejected.
- 2. If a data stream contains more than one instance of an entity that does not permit duplicates, the data stream is rejected.
- 3. If an entity violates the entity hierarchy (e.g., if *ICR* appears under *Budget*, instead of *Organization*), the data stream is rejected.
- 4. If an entity is required and an instance of the entity is not present in the data stream, the data stream is rejected.

The list of all required entities is provided below.

- Application
- Application.Individual (for types AD and 1B)
- Application.Organization (for types BY and SE)
- Application.Project
- Application.Project.Budget
- Application.Project.Budget_Budget_Period
- Application.Project.Budget_Budget_Period.Budget_Item
- Application.Project.Individual (for type 9P)
- Application.Project.Individual.Contact_Information (for Individual type 9P)
- Application.Project.Individual.Education (for Individual type 9P)
- Application.Project.Individual.Organization (for Individual type 9P)
- Application.Project.Animal_Subjects.IACUC
 - (if Application.Project.Animal_Subjects is present)
- Application.Project.Human_Subjects.IRB
 - (if Application.Project.Human_Subjects is present)
- Application.Project.Individual.Other_Support.Other_Support_Period (if Application.Project.Individual.Other_Support is present)
- Application.Project.Individual.Other_Support.Organization (if Application.Project.Individual.Other_Support is present)

In general, all information on the PHS 398 face page, except EIN, DUNS, and congressional district, and all information on the PHS 398 checklist, except program income, must be present.

2.5.2 Data Element Rules

- 1. If an entity contains a data element that is not recognized, the data stream is rejected.
- 2. If an entity contains more than one instance of a data element that does not permit duplicates, the data stream is rejected.
- 3. If a data element is required and an instance of the data element is not present in the entity, the data stream is rejected.
- 4. If a data element violates a length constraint, the data stream is rejected.
- 5. If a data element contains a code value that is not permitted, the data stream is rejected.

2.6 ASCII Text

When submitting grant application data to NIH via an HTML-stream, grantee organizations encode the data using the 7-bit American Standard Code for Information Interchange (ASCII) bit pattern. This encoding scheme does not permit the representation of many foreign language characters (e.g., the \ddot{A}). This limitation is most apparent when specifying abstracts, project titles and publication titles containing special characters (e.g., mathematical characters). For the HTML-stream pilot, NIH recommends providing a brief description of the special character. For example, use *delta* in lieu of δ , or use *small a, umlaut* in lieu of \ddot{a} .

3 Data Dictionary Implementation Guidelines

Grantee organizations can use HTML-formatted data streams to submit competing grant application data to NIH. Only one application can be submitted via a single data stream.

The following table lists the entities that comprise the grant application data dictionary. For each entity, attributes such as whether the entity is required and whether duplicate values are permitted are provided. Some entities categorize these attributes by type. For example, the ORGANIZATION entity representing the applicant organization (type SE) is required, and duplicates are not permitted. In contrast, the ORGANIZATION entity representing a performance site (type 61) is not required, and duplicates are permitted.

Note that the "Required" attribute for an entity must be viewed in relationship to the "Required" attribute for its parent entity. For example, OTHER_SUPPORT_PERIOD is required. OTHER_SUPPORT_PERIOD, however, is subordinate to OTHER_SUPPORT, which is not required. This means that the other support period must be provided only if other support is applicable.

Table 3-1. Competing Grant Application Entities

Entity Name	Required	Duplicates Allows
APPLICATION	Yes	No
ANIMAL_SUBJECT	No	No
BUDGET	Yes	No
BUDGET_ITEM	Yes	Yes
BUDGET_LABOR	No	Yes
BUDGET_PERIOD	Yes	Yes
CONTACT_INFORMATION (per person or organization)		
Types: 9P, AD, 1B, and SE	Yes	No
Types: all other organizations and persons	No	No
EDUCATION (per person)		
Type: 9P	Yes	Yes
Types: all other persons	No	Yes
EXTERNAL_ATTACHMENT	No	No
HUMAN_SUBJECT	No	No
IACUC	Yes	No
ICR	No	No
INDIVIDUAL (per type)		
Types: AD, 1B	Yes	No
Type: AZ	No	No
Type: 9P (PI)	Yes	No
Type: 9P (Other Support PI)	No	No
Type: 9K	No	Yes
IRB	Yes	No
MATRIX	No	No
ORGANIZATION (per type)		
Types: BY, SE	Yes	No
Type: 9P	Yes	No
Type: 9K	No	No
Type: 61	No	Yes
Type: 92	Yes	No
OTHER_SUPPORT	No	Yes
OTHER_SUPPORT_PERIOD	Yes	No
PARAGRAPH		
Types: D, D.1, D.2, D.3, D.4	No	No
Types: D.5, D.5.1	No	Yes
Types: A, B.2, C.2, C.3, E.4, F.2, I.6	No	No
Type: E.7	No	No
PROJECT	Yes	No
RACE_ETHNICITY	No	No
SOLICITATION_ANNOUNCEMENT	No	No
YES_NO_CONDITION	No	No

3.1 APPLICATION Entity Data Elements

The following table defines the data elements for the APPLICATION entity. If the APPLICATION entity is viewed as a database table, each data element is analogous to a column in the table.

For the application entity (as well as all other entities), the following information is provided:

- 1. Data Element Name the name of the data element.
- 2. Data Type the type of the data element. The following types are used:

AN Alphanumeric

DATE Format is CCYYMMDD (e.g., Jan 13, 2001 is 20010113)

DOLLAR Monetary Amount; format is nnnnnnnnn (maximum value is 10

digits)

ID Identifier (Alphanumeric, but values are predefined)

NUM Numeric (Treated as number or string, depending on context)

- 3. Min Len the minimum number of characters permitted for the data element.
- 4. Max Len the maximum number of characters permitted for the data element.
- 5. Dupl a Boolean indicating whether the data element can have multiple values.
- 6. Req a Boolean indicating whether the data element must be present.
- 7. Code List a list of permitted values for the data element.

Note that some attributes are bold and italic. These attributes have an NIH value that is different than the X12 194 transaction set value.

Table 3-2. Supported APPLICATION Data Elements

Data Element	Data Type	Min	Max	Dupl	Req	Code List
Name		Len	Len			
Purpose	ID	2	2	NO	YES	"00" Original
Applicant_Id	AN	1	30	NO	YES	
Use to cite the grant applicant's unique						
identifier for this application.						
Submission_Date	DATE	8	8	NO	YES	
Туре	ID	2	2	NO	YES	"6C" Competing Continuation
						"6R" Revision
Title	AN	1	81	NO	YES	
Appl_Number_of_Orig_Sub	AN	1	30	NO	NO	
Award_Id	AN	1	30	NO	NO	

3.2 ANIMAL_SUBJECT Entity Data Elements

The ANIMAL_SUBJECT entity has no relevant data elements for the competing grant application. It acts as the parent entity for the IACUC entity.

3.3 BUDGET Entity Data Elements

The BUDGET entity has no relevant data elements for the competing grant application. It acts as the parent entity for the BUDGET_PERIOD entity.

3.4 BUDGET_ITEM Entity Data Elements

Use the BUDGET_ITEM entity to specify items for the initial budget period and the proposed period of support. Also use to identify indirect costs.

Note 1. To specify multiple Indirect Cost Rates for a budget period, average the rates and bases and provide the averaged values. Providing an explanation is recommended.

Table 3-3. Supported BUDGET_ITEM Data Elements

Data Element	Data Type	Min	Max	Dupl	Req	Code List
Name		Len	Len			
Code	ID	2	2	NO	YES	"08" Other Base "09" Total Indirect Costs "38" Total Cost "39" Other Expenses "42" Equipment – Itemized "43" Supplies "46" Ancillary Service Contracts "47" Modified Total Direct Cost Base "48" Total Fringe Benefits Requested "51" Salary and Wages Base "52" Travel "70" Total Salaries Requested "71" Salary and Fringe Benefits "72" Equipment – Total "80" Publication Costs "81" Consultant Costs "82" ADP Services "84" Total Direct Costs "85" Inpatient Patient Care "86" Animal Costs "87" Alterations and Renovations "BL" Outpatient Patient Care "EH" Equipment Maintenance "RL" Rent/Lease Equipment/Facilities "ZZ" Off-Site Rate Base
Cost	DOLLAR	1	10	NO	NO	
Description	AN	1	80	NO	NO	
Quantity	NUM	1	15	NO	NO	
Percentage_Rate	NUM	1	15	NO	NO	

3.5 BUDGET_LABOR Entity Data Elements

Use the BUDGET_LABOR entity to specify information for a user on a project. Use one instance of this entity for each user on the current budget period and the proposed budget period. If the user has a GUIDe, specify it here. If not, cite an INDIVIDUAL entity subordinate to this entity to uniquely identify the user.

Note 1. For individuals with different percentages over different periods (e.g., different level of effort for academic period verses summer period), average the percentages for the individual.

Note 2. All people referenced on a project must be identified in the budget. All names for key personnel must be unique and must match the name provided in Application.Project.Individual.

Table 3-4. Supported BUDGET_LABOR Data Elements

Data Element	Data Type	Min	Max	Dupl	Req	Code List
Name		Len	Len			
GUIDe	AN	1	30	NO	NO	
Project_Role	AN	1	30	NO	NO	
Labor_Category	AN	1	30	NO	NO	
Level_Effort_Months	NUM	1	2	NO	NO	
Level_Effort_Percentage Calculate average over Level_Effort_Months	NUM	1	10	NO	NO	
Previous_Level_Effort_Percentage Calculate average over budget period.	NUM	1	10	NO	NO	
Salary	DOLLAR	1	10	NO	NO	
Requested_Salary	DOLLAR	1	10	NO	NO	
Requested_Benefits	DOLLAR	1	10	NO	NO	

3.6 BUDGET_PERIOD Entity Data Elements

Use the BUDGET_PERIOD entity to identify the requested budget period, including start date and length.

Table 3-5. Supported BUDGET_PERIOD Data Elements

Data Element	Data Type	Min	Max	Dupl	Req	Code List
Name		Len	Len			
Period_Id	AN	1	80	NO	YES	"T" Total Period
						"1" "2" "3" "4" "5" Support Years
Start_Date	DATE	8	8	NO	YES	
Length	NUM	1	20	NO	YES	
Provide number of months.						

3.7 CONTACT_INFORMATION Entity Data Elements

Use the CONTACT_INFORMATION entity to specify contact information for select individuals (i.e., PI, administrative official, and signing official), for the applicant organization, and for performance sites.

Note 1. The Street_Address, Zip_Code, Telephone_Number, Fax_Number, and Email_Address data elements are required for the project PI, administrative official, and signing official.

Note 2. Only specify the City, State, and Country data elements for a performance site.

Table 3-6. Supported CONTACT_INFORMATION Data Elements

Data Element	Data Type	Min	Max	Dupl	Req	Code List
Name		Len	Len			
Street_Address	AN	1	55	YES	NO	
A maximum of four street addresses						
can be specified.						
City	AN	2	30	NO	YES	
State	ID	2	2	NO	YES	
Zip_Code	ID	3	9	NO	NO	
Country	AN	2	3	NO	NO	ISO 3166
County	AN	1	30	NO	NO	
Telephone_Number	AN	1	25	NO	NO	
Fax_Number	AN	1	25	NO	NO	
Email_Address	AN	1	80	NO	NO	
Mail_Stop	AN	1	20	NO	NO	

3.8 EDUCATION Entity Data Elements

Use the EDUCATION entity to specify the academic degrees for the PI and key persons.

Table 3-7. Supported EDUCATION Data Elements

Data Element	Data Type	Min	Max	Dupl	Req	Code List
Name		Len	Len			
Туре	AN	2	5	NO	YES	See note 1.
Institution	AN	1	40	NO	YES	
Date	AN	6	6	NO	YES	
Use format CCYYMM						
Major	AN	1	80	NO	NO	
Specialization	AN	1	80	NO	NO	

1 NIH recognizes the following degrees for degree type:

AB	CHB	DNS	LLB	MLS	OD
AS	DC	DNSC	LLD	MN	PHB
BA	DDS	DO	LLM	MPH	PHD
BCH	DED	DPH	MA	MPHN	PHRM
BD	DENG	DSC	MB	MPM	RN
BENG	DHS	DSN	MBBS	MRCP	SCD
BM	DLS	DSW	MCHD	MS	VMD
BS	DMD	DVM	MCHR	MSCD	OTH (other)
BSD	DMS	DVS	MD	MSD	
BSN	DMSC	EDD	MDS	MSN	
BSNE	DN	HS	MEDS	MSNE	
BSW	DNED	JD	MENG	MSW	

3.9 EXTERNAL_ATTACHMENT Entity Data Elements

Use the EXTERNAL_ATTACHMENT entity to specify how the project plan is being transmitted to the Federal agency.

Note 1. When transmitting the project plan as an NIH HTTP file upload, set the Transmission_Type to "DA".

Note 2. When transmitting the project plan as an X12 102 transaction set, set the Transmission_Type to "EL", set the Transaction_Set_Id to "102", and set the Transaction_Number to the unique number for the related X12 102 transaction.

Table 3-8. Supported EXTERNAL_ATTACHMENT Data Elements

Data Element	Data Type	Min	Max	Dupl	Req	Code List
Name		Len	Len			
Туре	ID	2	2	NO	YES	"SD" Technical Data
Transmission_Type	ID	1	2	NO	YES	"BM" By Mail
						"DA" Data
						"EL" Electronically Only
Transaction_Set_Id	AN	1	30	NO	NO	"102"
Transaction_Number	AN	1	30	NO	NO	

3.10 HUMAN_SUBJECT Entity Data Elements

The HUMAN_SUBJECT entity has no relevant data elements for the competing grant application. It acts as the parent entity for the IRB and MATRIX entities.

3.11 IACUC Entity Data Elements

Use the IACUC entity to specify relevant vertebrate animal information.

Table 3-9. Supported IACUC Data Elements

Data Element	Data Type	Min	Max	Dupl	Req	Code List
Name		Len	Len			
Assurance_Number	AN	1	30	NO	NO	
Approval_Date	DATE	8	8	NO	NO	
Approval_Pending	AN	1	45	NO	NO	"Y" Yes
						"N" No

3.12 ICR Entity Data Elements

Use the ICR entity to specify indirect cost rate information, specifically the date of the agreement and/or the DHHS Regional Office or PHS Agency Cost Advisory Office with which the indirect cost rate was established.

Table 3-10. Supported ICR Data Elements

Data Element Name	Data Type	Min Len	Max Len	Dupl	Req	Code List
Filing_Location	AN	1	35	NO	NO	See Note 1.
Agree_Date	DATE	8	8	NO	NO	

- 1. When specifying the DHHS Regional Office at which an indirect cost rate has been negotiated, use the following codes:
 - "NE" Northeastern Office, New York, NY
 - "MID" Mid-Atlantic Office, Washington, DC
 - "CEN" Central States Office, Dallas, TX
 - "WES" Western States Office, San Francisco, CA

If an indirect cost rate has been negotiated at a different agency's cost advisory office, cite the name of the office.

3.13 INDIVIDUAL Entity Data Elements

Use the INDIVIDUAL entity to identify the project PI, key personnel, an other support PI, a former PI (if the PI has changed), and the administrative and signing officials for the applicant organization.

Note 1. For types 9P, 1B, and AD, the Title data element is required.

Note 2. For the "Other Support PI", the maximum length for all the name attributes is 60 characters.

Table 3-11. Supported INDIVIDUAL Data Elements

Data Element	Data Type	Min	Max	Dupl	Req	Code List
Name		Len	Len			
Type	ID	2	2	NO	YES	"1B" Signing Official
						"AD" Administrative Officer
						"9K" Key Person
						"9P" Principal Investigator
						"EY" Employee (non-key person)
						"AZ" Former Principal Investigator
Last_Name	AN	1	<i>30</i>	NO	YES	
First_Name	AN	1	25	NO	NO	
Middle_Name	AN	1	25	NO	NO	
Prefix	AN	1	10	NO	NO	
Suffix	AN	1	5	NO	NO	
GUIDe	ID	1	30	NO	NO	
SSN	ID	1	30	NO	NO	
Title	AN	1	40	NO	NO	
Birth_Date	DATE	8	8	NO	NO	
Sex	ID	1	1	NO	NO	"A" Not Provided
						"F" Female
						"M" Male

3.14 IRB Entity Data Elements

Use the IRB entity to specify relevant human subject information.

Table 3-12. Supported IRB Data Elements

Data Element	Data Type	Min	Max	Dupl	Req	Code List
Name		Len	Len			
Review_Type	AN	1	45	NO	NO	"Full"
						"Expedited"
Assurance_Number	AN	1	30	NO	NO	
Approval_Date	DATE	8	8	NO	NO	
Exemption_Number	AN	1	30	YES	NO	
Approval_Pending	AN	1	45	NO	NO	"Y" Yes
						"N" No

3.15 MATRIX Entity Data Elements

Use the MATRIX entity to specify the Gender and Minority Inclusion table. Construct the matrix as follows:

Rows: 1 (Male), 2 (Female), 3 (Unknown)

Cols: A (Indian), B (Asian), C (Black), D (Hispanic), E (White), F (Other)

Table 3-13. Supported MATRIX Data Elements

Data Element	Data Type	Min	Max	Dupl	Req	Code List
Name		Len	Len			
Start_Cell	AN	1	30	NO	YES	"A1"
End_Cell	AN	1	30	NO	YES	
Data	AN	1	80	YES	YES	
Title	AN	1	60	NO	NO	

3.16 ORGANIZATION Entity Data Elements

Use the ORGANIZATION entity to specify information pertaining to the various organizations referenced on the application.

- *Note 1.* Only cite the DUNS data element when identifying NIH as the Federal agency (type BY).
- *Note 2.* The Name and Entity_Type data elements are required for the applicant organization (type SE).
- *Note 3.* The Division and Department data elements are only to be provided for the organization of the PI (type 9P), and are required.

Note 4. Only cite the Name data element for a performance site (type 61) or an other support organization (type 92). Only provide performance site data if there is a change. If any performance site data has changed, all performance site information must be resubmitted.

Table 3-14. Supported ORGANIZATION Data Elements

Data Element	Data Type	Min	Max	Dupl	Req	Code List
Name		Len	Len		_	
Туре	ID	2	2	NO	YES	"BY" Federal Agency
						"61" Performance Site
						"SE" Grant Applicant
						"92" Other Support
						"9P" Organization of PI
						"9K" Organization of key person
Name	AN	1	40	NO	NO	
DUNS	AN	2	80	NO	NO	
Division	AN	1	30	NO	NO	
Profile_Id	AN	1	30	NO	NO	
EIN	AN	1	30	NO	NO	
Department	AN	1	30	NO	NO	
Congressional_District	AN	1	2	NO	NO	
Entity_Type	ID	2	3	NO	NO	"2R" Federal Facility
						"2F" State
						"C6" Local / Municipality
						"A8" Nonprofit Institution
						"B9" Large Business
						"21" Small Business

3.17 OTHER_SUPPORT Entity Data Elements

Use the OTHER_SUPPORT entity to identify active and pending other support projects. Identify other support only for key personnel on the proposed budget period.

Table 3-15. Supported OTHER_SUPPORT Data Elements

Data Element	Data Type	Min	Max	Dupl	Req	Code List
Name		Len	Len			
Туре	ID	2	2	NO	YES	"37" Active
						"A3" Pending
Annual_Cost	DOLLAR	1	10	NO	YES	
Award_Number	AN	1	30	NO	NO	
Application_Number	AN	1	30	NO	NO	
Major_Goals	AN	1	700	NO	NO	
Overlap	AN	1	700	NO	NO	
Summarize overlap for all OS						
projects on a per individual basis.						
Title	AN	1	60	NO	NO	

3.18 OTHER_SUPPORT_PERIOD Entity Data Elements

Use the OTHER_SUPPORT_PERIOD entity to identify the dates and percent effort associated with an active other support project.

Table 3-16. Supported OTHER_SUPPORT_PERIOD Data Elements

Data Element	Data Type	Min	Max	Dupl	Req	Code List
Name		Len	Len			
Start_Date	DATE	8	8	NO	YES	
End_Date	DATE	8	8	NO	YES	
Level_Effort_Percentage Calculate the average over the Other Support Period	NUM	1	10	NO	NO	

3.19 PARAGRAPH Entity Data Elements

Use the PARAGRAPH entity to specify freeform text.

Note 1. To identify that an invention was conceived under this project, cite I.6 in the Type data element. Also, cite the word "Reported" in the Text data element if the invention was previously reported. If the invention was not previously reported, cite the phrase "Not Reported" in the Text data element.

Note 2. For biographical information (types "D.1" – "D.4") and publications (types "D.5" and "D.5.1"), identify each different instance or publication in a separate iteration of the Paragraph entity (e.g., use two distinct instances of the Paragraph entity to identify two different employment positions).

Note 2. To specify research and profession experience, use either Type code "D" (for all information) or Type codes "D.1" through "D.4" (for itemized information).

Table 3-17. Supported PARAGRAPH Data Elements

Data Element	Data Type	Min	Max	Dupl	Req	Code List
Name		Len	Len			
Туре	ID	1	4	NO	YES	"A" Abstract (20K)
						"B.2" Specific Aims (20K)
						"C.1" Budget Justification (2K)
						"C.2" Space/Facilities (20K)
						"C.3" Equipment (20K)
						"D" Biographical (20K)
						"D.1" Experience (2K)
						"D.2" Employment History (2K)
						"D.3" Honors (512 char)
						"D.4" Memberships/Associations
						(512 char)
						"D.5" Publication Text (20K)
						"D.5.1" Medline Accession Number
						"E.4" Program Income (100 char)
						"E.7" Indirect Cost Base (20K)
						"F.2" Cover Letter (20K)
						"I.6" Inventions
Title	AN	1	30	NO	NO	
Text	AN	1	N/A	NO	YES	

3.20 PROJECT Entity Data Elements

Use the PROJECT entity to identify the start and end dates for a project. The PROJECT entity also acts as the parent for all other project-related entities.

Table 3-18. Supported PROJECT Data Elements

Data Element	Data Type	Min	Max	Dupl	Req	Code List
Name		Len	Len			
Туре	ID	1	2	NO	YES	"PC" Project
Start_Date	DATE	8	8	NO	YES	
End_Date	DATE	8	8	NO	NO	
Duration	NUM	1	2	NO	NO	
Cite number of months						

3.21 RACE_ETHNICITY Entity Data Elements

Use the RACE_ETHNICITY entity to specify the race/ethnicity of the project PI.

Table 3-19. Supported RACE_ETHNICITY Data Elements

Data Element	Data Type	Min	Max	Dupl	Req	Code List
Name		Len	Len			
Type	ID	1	1	NO	YES	"7" Not Provided
						"A" Asian or Pacific islander
						"B" Black
						"C" Caucasian
						"H" Hispanic
						"I" American Indian or Alaskan Native
						"P" Pacific Islander

3.22 SOLICITATION_ANNOUNCEMENT Entity Data Elements

Use the SOLICITATION_ANNOUNCEMENT entity to identify the number and title of the Request For Application or Program Announcement to which this application is a response.

Table 3-20. Supported SOLICITATION_ANNOUNCEMENT Data Elements

Data Element Name	Data Type	Min Len	Max Len	Dupl	Req	Code List
Number	AN	1	30	NO	YES	
Title	AN	1	50	NO	NO	

3.23 YES_NO_CONDITION Entity Data Elements

Use the YES_NO_CONDITION entity to answer questions relating to assurances and certifications, and whether the PI is a new investigator. Only provide when the response to codes H4, I7, I8, or J.1 is *Yes*, or when the response to codes H0, H5, H6, H7, H8, or H9 is *No*.

Table 3-21. Supported YES_NO_CONDITION Data Elements

Data Element	Data Type	Min	Max	Dupl	Req	Code List
Name	_	Len	Len			
Type	ID	2	2	NO	YES	"H0" Certifies Compliance With
						Federal Lobbying Regulations
						"H4" Lobbying Activities Have Been
						Conducted Regarding the Proposal
						"H5" Certifies Compliance With the Drug-Free
						Workplace Act
						"H6" Certifies Compliance With the Code of
						Federal Regulations Regarding Research
						Misconduct
						"H7" Organization Provides a Smoke Free
						Workplace
						"H8" Certifies Compliance With Federal
						Discrimination Regulations
						"H9" Certifies Compliance With the Code of
						Federal Regulations Regarding Responsibility
						of Applicants for Promoting Objectivity in
						Research
						"I7" Delinquent Federal Debts
						"I8" Federal Debarment and Suspension List
						"J.1" New Investigator
Response	ID	1	1	NO	YES	"Y" Yes
						"N" No
Condition_Date	DATE	8	8	NO	NO	
Description	AN	1	264	NO	NO	

4 HTML-Formatted Data Stream Syntax

The syntax for HTML-streams is based on the data stream produced when a user *submits* (i.e., selects the *submit* button on) a Web form. Upon submission of a Web form, a data stream is generated such that the information input by the user is represented by a sequence of *key/value* pairs. The *key* portion is the variable name assigned by the Web form creator. The *value* portion is the information entered by the user submitting the form.

An example helps clarify this concept. Assume that a Web form contains a text box for entering a person's last name, that the form creator assigns the variable name *Name_Last* to the text box, and that the user enters the name *Ptolemy* in the text box. When the user submits the form, the resulting data stream for that text box is:

As seen from this trivial example, the HTML-formatted data stream syntax has two components:

- a set of permitted variable names (these are the data element names defined in the grant application data dictionary), and
- a set of rules for combining these data elements (i.e., a grammar)

4.1 Data Element Rules

There are certain rules and restrictions when specifying the *value* portion of data elements. The following rules and restrictions are carried over from the X12 194 transaction set.

- 1. When specifying numerical data elements, special formatting characters must not be included. For example, telephone numbers must not contain parentheses or dashes, and social security numbers, DUNS numbers, grant numbers, and 9-digit zip codes must not contain dashes.
- 2. Monetary amounts must not contain the dollar sign.

Other rules are specific to HTML-streams. These rules and restrictions are listed below.

- 1. Entities and data element names are not case sensitive.
- 2. Spaces are specified with the character "+". For example, the name "Tycho Brahe" is represented as "Tycho+Brahe".
- 3. There are certain *special characters* in HTML-streams. When representing these special characters as text in the data element *value* portion, they must be specified as a multi-character sequence. The following table lists each special character and its

associated multi-character sequence. Note that when determining the length of a data element value, each special character is counted as one character, despite its multi-character representation.

Table 4-1. Specifying Special Characters

Description	Character	Specification in Data Stream
ampersand	&	&
less-than	<	<
greater-than	>	>
Quotation mark	"	"
plus	+	& #43;
semi-colon	;	% #59;
tab		& #09;
new line		

4.2 Grammar Rules

Section 4.1 provides the information necessary to specify any single data element. This section provides the rules for specifying a sequence of data elements as an HTML-stream.

4.2.1 Basic Rules

There are 5 basic rules for combining data elements into an HTML-stream.

- 1. The HTML-stream is a continuous sequence of data elements; no white space is permitted between data elements.
- 2. All data elements must appear within an entity.
- 3. Entities can appear in any order (within the constraints of the relevant hierarchy).
- 4. Data elements comprising an entity can appear in any order.
- 5. The delimiter between data elements is the character "&".

4.2.2 Specifying Entities With Multiple Values

Many entities permit duplicates. This simply means that there can be multiple instances of an entity. For example, one instance of the ORGANIZATION entity can be used to specify one performance site on an application. To specify a second performance site on the organization, a second instance of the entity is used.

To better understand how entities that allow duplicates are handled within an HTML-stream, the entities should be viewed as tables in a relational database. The set of data elements that comprise an entity is represented as a row in that table. To delineate between tables (i.e., entities) and rows within a table (i.e., instances of an entity) the *Ordered/Boundary Method* [5] is employed.

The Ordered / Boundary Method uses the tags BEGIN and END to delineate tables, and the tag NEXT to delineate rows within a table. For example, given the following data elements in the INDIVIDUAL table:

Table 4-2. Example Table for BEGIN, NEXT, and END Tags

Туре	Last Name	First Name
1B	Bruno	Giordano
AD	Brahe	Tycho

the resulting HTML-stream is:

BEGIN=INDIVIDUAL
&Type=1B
&Last_Name=Bruno
&First_Name=Giordano
&NEXT= INDIVIDUAL
&Type=AD
&Last_Name=Brahe
&First_Name=Tycho
&END= INDIVIDUAL

Note that the HTML-stream would be one continuous stream. The above formatting is provided only for readability.

4.2.3 Specifying Data Elements With Multiple Values

Some data elements are permitted multiple values. For example, an individual's mailing address can have multiple street address lines. To identify multiples values associated with a data element, simply repeat the data element for each value. This concept is reflected in the following table and data stream, which provides CONTACT_INFORMATION for the user Tycho Brahe from the previous example.

Table 4-3. Example Table for Multiple Data Element Values

Street Address1	Street Address2	City	State
1234 Main St	Suite 501	Bethesda	MD

The resulting HTML-stream becomes:

```
BEGIN=INDIVIDUAL
&Type=AD
&Last_Name=Brahe
&First_Name=Tycho
&BEGIN= CONTACT_INFORMATION
&Street_Address=1234+Main+St
&Street_Address=Suite+501
&City=Bethesda
&State=MD
&END= CONTACT_INFORMATION
&END= INDIVIDUAL
```

Again, the formatting is provided only for readability.

Appendix A. Sample PHS 398 Application and 194 Transaction Set

This appendix contains a sample PHS 398 application. The sample application is followed by the corresponding HTML-stream.

The sample PHS 398 application contains fictitious information. Although the application data is *realistic* in format, it should not be used as guidance for completing a 398 application. The purpose of the sample application is to illustrate the relationship between 398 form data elements and HTML-stream data elements.

Also, note that within the data stream certain data elements are italic and bold. These data elements are mapped directly to fields in an NIH database.

Form Approved Through 2/28/01 OMB No. 0925-0001 LEAVE BLANK—FOR PHS USE ONLY. Department of Health and Human Services Public Health Services Type Activity Number

Grant Application	on	Review Group					
Follow instructions carefully. Do not exceed character length restrictions ind		Council/Board (Month, Ye	ear)	Date Receive	ed		
TITLE OF PROJECT (Do not exceed 56 character)		unctuation.)					
Atherosclerosis Prevention Study							
RESPONSE TO SPECIFIC REQUEST FOR APPL Number: Title:	LICATIONS OR PROGRAM	M ANNOUNCEMENT x NC	YES (If "Ye	s," state num	nber and title)		
	'O.D.	N ew Investigator	VEC				
3. PRINCIPAL INVESTIGATOR/PROGRAM DIRECT 3a. NAME (Last, first, middle)	OR	3b. DEGREE(S)		3c SOCIAL	SECURITY NO.		
Galilei, Galileo, N.	B.S., M.D.			on Form Page KK.			
3d. POSITION TITLE		3e. MAILING ADDRESS	(Street, city, s				
Professor of Medicine		University of Bethe			,		
3f. DEPARTMENT, SERVICE, LABORATORY, OR E	QUIVALENT	Atherosclerosis Re					
MDK		461 Ocean Blvd., N	MSC-32				
3g. MAJOR SUBDIVISION		Bethesda, MD 208	92				
01							
3h. TELEPHONE AND FAX (Area code, number and TEL: (301) 555 1478	extension)	E-MAIL ADDRESS:					
TEL: (301) 555 1478 FAX: (301) 555 2685		ggalilei@ub.edu					
4. HUMAN 4a. If "Yes," Exemption no.		5. VERTEBRATE					
SUBJECTS or	4b. Assurance of	ANIMALS	5a. If "Yes,"		5b. Animal welfare		
No IRB approval date Full IRB g	compliance no.	No	IACUC ap date	oprovai	assurance no.		
x Yes Pending Expedited	W1234307D	x Yes	02/01/	/97	A9999-01		
6. DATES OF PROPOSED PERIOD OF	7. COSTS REQUESTED				OR PROPOSED		
SUPPORT (month, day, year—MM/DD/YY)	BUDGET PERIOD	FOR INITIAL		F SUPPORT	OK PROPOSED		
From Through	7a. Direct Costs (\$)	7b. Total Costs (\$)	8a. Direct Costs	s (\$)	8b. Total Costs (\$)		
04/01/98 03/31/00	\$470,757	\$713,196	\$1,098	,404	\$1,664,082		
9. APPLICANT ORGANIZATION		10. TYPE OF ORGANIZATION					
Name University of Bethesda Address 461 Ocean Blvd.		Public: → Federal State Local Private: → x Private Nonprofit					
Bethesda, MD 20892			•	mall Business			
		11. ORGANIZATIONAL			01		
IPF # 1234567 DUNS # 112233445		12. ENTITY IDENTIFICATION			Congressional District		
13. ADMINISTRATIVE OFFICIAL TO BE NOTIFIED II	F AWARD IS MADE	012345 14. OFFICIAL SIGNING		TION ORGAN	NIZATION		
Name Tycho H. Brahe		Name Giordano Bru	no Jr.				
Title Deputy Director		Title Provost & Sei			airs		
Address Dept of Contracts and Grants 1313 Mockingbird Lane, DEI-5555		Address Dept of Contracts and Grants					
Bethesda, MD 20892	1313 Mockingbird Lane, DEI-5555 Bethesda, MD 20892 Phone (301) 555 2390						
Telephone (301) 555 2396							
FAX (301) 555 2835		FAX (301) 555	5 4414				
E-Mail tbrahe@munster.ub.edu Address	E-Mail giordano.bruno@ub.edu Address						
 PRINCIPAL INVESTIGATOR/PROGRAM DIRECT I certify that the statements herein are true, complete a 	SIGNATURE OF PI/PD NAMED IN 3a. (In ink. DATE						
my knowledge. I am aware that any false, fictitious, of	"Per" signature not accept	lable.)					
claims may subject me to criminal, civil, or administration accept responsibility for the scientific conduct of the							
required progress reports if a grant is awarded as a resu							
16. APPLICATION ORGANIZATION CERTIFICATION	SIGNATURE OF OFFICIA		4 (In ink.	DATE			
I certify that the statements herein are true, complete an my knowledge, and accept the obligation to comply with	Public Health Services	"Per" signature not accept	ault.)				
terms and conditions if a grant is awarded as a result of aware that any false, fictitious, or fraudulent statements					06/02/97		
to criminal, civil, or administrative penalties.	2. 2.3oa, oubject me						
DUI 000 (D 1/00)	_	_			Λ Λ		

DESCRIPTION: State the application's broad, long-term objectives and specific aims, making reference to the health relatedness of the project. Describe concisely the
research design and methods for achieving these goals. Avoid summaries of past accomplishments and the use of the first person. This abstract is meant to serve as a
succinct and accurate description of the proposed work when separated from the application. If the application is funded, this description, as is, will become public information.
Therefore, do not include proprietary/confidential information. DO NOT EXCEED THE SPACE PROVIDED.
This is where the abstract would go

This is where the abstract would go.
PERFORMANCE SITE(S) (organization city state)

Pharmacology Research Laboratory, Bethesda, MD USA

KEY PERSONNEL. See instructions on Page 11. Use continuation pages as needed to provide the required information in the format shown below.

Name Role on Project Organization

Galilei, Galileo Principal Investigator University of Bethesda Copernicus, Nicholas University of Bethesda Research Assistant Newton, Isaac University of Bethesda Staff Scientist

DETAILED BU	JDGET FOR INITIA DIRECT COSTS		ET PERIC)D	FROM 04/0	1/98	THROUGH 03/31/99
PERSONNEL (Applicant organization only)			%		DOLLAR	AMOUNT REQU	ESTED (omit cents)
NAME	ROLE ON PROJECT	TYPE APPT. (months)	EFFORT ON PROJ.	INST. BASE SALARY	SALARY REQUESTED	FRINGE BENEFITS	TOTAL
Galilei, Galileo	Principal Investigator	12	40	\$110,000	\$44,000	\$13,772	\$57,772
Copernicus, Nicholas	Research Assistant	9	20	\$119,719	\$11,972	\$3,747	\$15,719
Copernicus, Nicholas	Research Assistant	2	100	\$119,719	\$26,602	\$8,326	\$34,928
Newton, Isaac	Staff Scientist	12	10	\$125,000	\$0	\$0	\$0
Keplar, Johannes	Supportee	12	50	\$25,331	\$12,666	\$3,964	\$16,630
TBD	Supportee	12	100	\$35,000	\$35,000	\$10,955	\$45,955
TBD	Lab Technician	12	100	\$32,000	\$32,000	\$9,600	\$41,600
TBD	Lab Technician	12	100	\$36,000	\$36,000	\$10,800	\$46,800
	SUBTOTALS				\$198,240	\$61,164	\$259,404
CONSULTANT COSTS							
							\$22,400
EQUIPMENT (Itemize) Single cell Perfusion Chambers and Centrifuge \$15,000	Filter Sets \$5,500						
							\$20,500
SUPPLIES (Itemize by category) Office, postage, and xerographical subject the subject in the subject is supplied to the subject is supplied to the subject in the subject is supplied to the subject is subject in the subject in the subject is subject in the subject is subject in the s	upplies for Clinic, Biosta	atisical, and	Administrativ	ve components \$4	000		25.400
ΓRAVEL							\$5,400
Fravel to National meetings for 3 indi	ividuals						\$4,000
PATIENT CARE COSTS	INPATIENT						\$3,500
	OUTPATIENT						\$84,720
ALTERATIONS AND RENOVATION	S (Itemize by category,)					
OTHER EVERYOPE "							\$28,750
OTHER EXPENSES (Itemize by cat Equipment Maintenance \$1,183; Po); Animal C	osts \$4,400;	Other Expenses	\$35,000		
							\$42,083
SUBTOTAL DIRECT COSTS	FOR INITIAL BU	DGET PE	RIOD			\$	\$470,757
CONSORTIUM/CONTRACTUAL	DIRECT COSTS						
COSTS	INDIRECT COSTS						
TOTAL DIRECT COSTS FOR	R INITIAL BUDGE	T PERIO	D (Item 7a, I	Face Page)		_ \$	\$470,757

BUDGET FOR ENTIRE PROPOSED PROJECT PERIOD DIRECT COSTS ONLY

BUDGET C	CATEGORY	INITIAL BUDGET PERIOD	AI	DDITIONAL YEARS OF	SUPPORT REQUESTED)
тот	ALS	(from Form Page 4)	2nd	3rd	4th	5th
PERSONNEL: S benefits Applicant organia		\$259,404	\$465,898			
CONSULTANT (COSTS	\$22,400	\$23,296			
EQUIPMENT		\$20,500				
SUPPLIES		\$5,400	\$5,616			
TRAVEL		\$4,000	\$4,098			
PATIENT CARE	INPATIENT	\$3,500				
COSTS	CARE	\$87,648				
ALTERATIONS ARENOVATIONS		\$28,750				
OTHER EXPENS	SES	\$42,083	\$41,091			
SUBTOTAL DIR	ECT COSTS	\$470,757	\$627,647			
CONSORTIUM/ CONTRACTUAL	DIRECT					
COSTS	INDIRECT					
TOTAL DIREC	CT COSTS	\$470,757	\$627,647			

TOTAL DIRECT COSTS FOR ENTIRE PROPOSED PROJECT PERIOD (Item 8a, Face Page)

\$ 1,098,404

JUSTIFICATION. Follow the budget justification instructions exactly. Use continuation pages as needed.

This is where the budget justification would go.

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel in the order listed for Form Page 2. Photocopy this page or follow this format for each person.

NAME	POSITION TITLE
Galilei, Galileo	Professor of Medicine

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)						
INSTITUTION AND LOCATION	DEGREE (if applicable)	YEAR(s)	FIELD OF STUDY			
University of Northern Italy University of Pisa	BS MD	1959 1963	Medicinal Chemistry Medicine			

RESEARCH AND PROFESSIONAL EXPERIENCE: Concluding with present position, list, in chronological order, previous employment, experience, and honors. Include present membership on any Federal Government public advisory committee. List, in chronological order, the titles, all authors, and complete references to all publications during the past three years and to representative earlier publications pertinent to this application. If the list of publications in the last three years exceeds two pages, select the most pertinent publications. **DO NOT EXCEED TWO PAGES.**

Experience:

1963-1965: University of California, Los Angeles. Department: Medicine. Resident.

1965-1974: University of California, Los Angeles. Department: Medicine. Medical Resident. 1974-1979: University of California, Los Angeles. Department: Medicine. Chief Resident.

1979-1992: University of California, San Diego. Department: Medicine. Associate Professor of

Medicine.

1992-1997: University of Bethesda. Department: Medicine. Professor of Medicine.

Honors:

Years: 1994-1995 JM Osbourne Preventive Medicine Award

Years: 1995-1996 American Society for Immunology Travel Award

Memberships:

Federal Advisory Committee Membership.

Agency: NIDDK Title: GMA-2 Study Section Start Year: 01/01/93 End Year: 01/01/1997

Publications:

- 1. Galilei, G., Brown C (1997). The pathogenesis of coronary disease. New England Journal of Medicine, 236: 142-150.
- 2. Galilei, G., Robin, C. (1995). Triggering of plague disruption. Circulation, 81: 576-584.
- 3. Galilei, G., Dilbert D. (1995) Arterial imaging and atherosclerosis reversal. Arterioscler Thromb. 14: 77-92.

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel in the order listed for Form Page 2. Photocopy this page or follow this format for each person.

NAME	POSITION TITLE
Copernicus, Nicholas	Clinical Investigator

DEGREE (if applicable)	YEAR(s)	FIELD OF STUDY
BS	1979	Biological Chemistry
PhD	1983	Biological Chemistry
	BS	(if applicable) BS 1979

RESEARCH AND PROFESSIONAL EXPERIENCE: Concluding with present position, list, in chronological order, previous employment, experience, and honors. Include present membership on any Federal Government public advisory committee. List, in chronological order, the titles, all authors, and complete references to all publications during the past three years and to representative earlier publications pertinent to this application. If the list of publications in the last three years exceeds two pages, select the most pertinent publications. **DO NOT EXCEED TWO PAGES.**

Experience:

1983-1986: National Institute of Allergy/Infectious Disease. Department: Lab of Clinical Investigation. Visiting Fellow.

1986-1992: University of Bethesda. Department: Medicine. Medical Resident. 1992-1997: University of Bethesda. Department: Medicine. Clinical Investigator.

Membership:

Agency: DRG NIH. Title: Ad hoc reviewer GMA-2 Study Section. Start year: 01/01/96

Publications:

- 1. Copernicus, N., Pooh W. (1997) Risk factor assessment and prevention of coronary artery disease. J Intern Med.;263:211-3.
- 2. Copernicus, N., McDonald R. (1997) Cholesterol Lowering Atherosclerosis Study (CLAS). Controlled Clin Trials. 18:156-87.

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel in the order listed for Form Page 2. Photocopy this page or follow this format for each person.

NAME	POSITION TITLE
Newton, Issac	Biostatistician

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)						
INSTITUTION AND LOCATION	DEGREE (if applicable)	YEAR(s)	FIELD OF STUDY			
New University College, London	BS	1975	Mathematics			
New University College, London	MS	1978	Mathematics			
Cambridge University	PhD	1982	Biometry			

RESEARCH AND PROFESSIONAL EXPERIENCE: Concluding with present position, list, in chronological order, previous employment, experience, and honors. Include present membership on any Federal Government public advisory committee. List, in chronological order, the titles, all authors, and complete references to all publications during the past three years and to representative earlier publications pertinent to this application. If the list of publications in the last three years exceeds two pages, select the most pertinent publications. **DO NOT EXCEED TWO PAGES.**

Experience:

1982-1984: Jackson Memorial Hospital, Department: Medicine. Staff Research Associate.

1984-1988: University of Illinois, Medical School. Department: Medicine. Associate Specialist.

1988-1997: University of Bethesda. Department: Medicine. Associate Professor of Biometry.

Publications:

Newton, I., Greenjeans, M. (1996) Effects of colestipol-niacin therapy on atherosclerosis. Circulation. 38:138-47.

Other Support

GALILEI, G.

<u>ACTIVE</u>

2 R01 HL 00000-13 (Galilei) 3/1/96 - 2/28/99 30% NIH/NHLBI \$186,529

Chloride and Sodium Transport in Airway Epithelial Cells

The major goals of this project are to define the biochemistry of chloride and sodium transport in airway epithelial cells and clone the gene(s) involved in transport.

PENDING

DCB 950000 (Galilei) 12/01/98-11/30-00 20% National Science Foundation \$82,163

Liposome Membrane Composition and Function

The major goals of this project are to define biochemical properties of liposome membrane components and maximize liposome uptake into cells.

OVERLAP

There is scientific overlap between aim 2 of NSF DCB 950000 and aim 4 of the application under consideration. If both are funded, the budgets will be adjusted appropriately in conjunction with agency staff.

COPERNICUS, N.

NONE

NEWTON, I.

ACTIVE

Investigator Award (Newton) 9/1/97 - 8/31/01 70% Howard Hughes Medical Institute \$581,317

Gene Cloning and Targeting for Neurological Disease Genes

This award supports the PI's program to map and clone the gene(s) implicated in the development of Alzheimer's disease and to target expression of the cloned gene(s) to relevant cells.

OVERLAP

None

RESOURCES

FACILITIES: Specify the facilities to be used for the conduct of the proposed research. Indicate the performance sites and describe capabilities, pertinent capabilities, relative proximity, and extent of availability to the project. Under "Other," identify support services such as machine shop, electronics shop, and specify the extent to which they will be available to the project. Use continuation pages if necessary.

Laboratory: X

These studies will be performed in the laboratory of Dr. Galilei. Dr. Galilei's laboratory is located in the Clinical Research Center of the University of Bethesda. The laboratory contains sinks, benches, refrigerators, and freezers for in vitro studies.

Clinical: X

There is full access to patients at the Pharmacology Research Laboratory in Bethesda, MD. In addition, there is support of community physicians.

Animal: X

There are animal housing and procedure rooms in the Clinical Research Center. This facility is staffed by veterinarians and animal husbandry personnel.

Computer: X

Dr. Galilei's laboratory contains a network of Pentium PCs with two color laser printers. The network has direct access to the Internet via the University of Bethesda backbone.

Office: X

There are several offices adjacent to Dr. Galilei's laboratory with desks, bookshelves, filing cabinets and computer systems. These can be used by both investigators and administrative personnel.

Other:

N/A

MAJOR EQUIPMENT: List the most important equipment items already available for this project, noting the location and pertinent capabilities of each.

The Clinical Research Center contains the following:

Liquid scintillation counter, ultracentrifuge, refrigerated centrifuge, C02 incubator, radioisotope detector, microscopes, balances, and a digital imaging system with computer control and perfusion equipment.

Principal Investigator/Program Director (Last, first, middle):

	CHECI	KLIST					
TYPE OF APPLICATIONS (Check all that	t apply.)						
NEW application. (This application is being submitted to the PHS for the first time.)							
REVISION of application number: (This application replaces a prior unfunded version of a new, competing continuation, or supplemental application.)							
, ,,	INVENTIONS AND PATENTS (Competing continuation appl. only)						
X COMPETING CONTINUATION of gran (This application is to extent a funde	5 R01 Al00000-01A ² d grant beyond its current project period.)		No X Previously reported s. If "Yes," Not previously reported				
SUPPLEMENT to grant number:							
(This application is for additional fund	ds to supplement a currently funded grant.)						
X CHANGE of principal investigator/progr Name of former principal investigato		nidt					
FOREIGN application or significant for	oreign component.						
1. ASSURANCES/CERTIFICATIONS		•Human Subject	ts; •Vertebrate Animals; •Debarment and Suspension; •Drug- Fre				
Official Signing for Application Organization Descriptions of individual	e made and verified by the signa- ture of the tion on the Face Page of the application. assurances/certifications begin on compliance where application, provide and	Workplace (app •Lobbying; •Delir 441 or HHS 69 Discrimination (F	collication to new [Type 1] or revised [Type 1] applications only inquent Federal Debt; •Research Misconduct; •Civil Rights (Form HH. 20); •Handicapped Individuals (Form HHS 641 or HHS 690); •Se Form HHS 639-A or HHS 690); •Age Discrimination (Form HHS 680 of ancial Conflict of Interest.				
PROGRAM INCOME (See instructions All applications must indicate whether anticipated, use the format below to reflect	er program income is anticipated during	the period(s) 1	for which grant support is request. If program income i				
Budget Period	Anticipated Amount		Source(s)				
04/01/98-03/31/99	\$50,000		Howard Hughes Medical Institute				
3. INDIRECT COSTS Indicate the applicant organization's most recent indirect cost rate established with the appropriate DHHS Regional Office, or, in the case of for profit organizations, the rate established with the appropriate PHS Agency Cost Advisory Office. If the applicant organization is in the process of initially developing or renegotiating a rate, or has established a rate with another Federal agency, it should, immediately upon notification that an award will be made, develop a tentative indirect cost rate established for profit organizations, the rate established with the appropriate PHS Agency Cost Advisory Office. Indirect costs will not be paid on foreign grants, construction grants, grants to Federal organizations, grants to individuals, and conference grants. Follow any additional instructions provided for Research Career Awards, Institutional National Research Service Awards, and submitted to the appropriate DHHS Regional Office or PHS Agency Cost Advisory Office. Indirect costs will not be paid on foreign grants, construction grants, construction grants, construction grants, prants to Federal organizations, grants to individuals, and conference grants. Follow any additional instructions provided for Research Career Awards, and specialized grant applications.							
X DHHS Agreement dated: 01/0	01/98		No Indirect Costs Requested.				
DHHS Agreement begin negotiated	with		Regional Office.				
No DHHS Agreement, but rate estab	olished with		Date				
	application, including the Checklist, will irect costs is optional for forprofit organizations.		and provided to peer reviewers as confidential information				
a. Initial budget period:	Amount of base \$ _ 470,757	x Rate applied	d <u>51.50</u> % = Indirect costs (1) \$ <u>242,439</u>				
b. Entire proposed project period: (1) Add to total dir.	Amount of base \$1,098,404 ect costs from form page 4 and enter new total	x Rate applied					
(2) Add to total dire	ect costs from form page 5 and enter new total	•					
*Check appropriate box(es): Salary and wages base	X Modified total direct cost b	ase	Other base (Explain)				
Off-site, other special rate, or more the	han one rate involved (Explain)						
Explanation (Attach separate sheet, if nec	cessary.):						
SMOKE-FREE WORKPLACE Does your organization currently provide a	smoke-free workplace and/or promote the nor	nuse of tobacco pr	roducts or have plans to do so?				
X Yes	onse to this question has no impact on the review		nis application.)				
PHS 398 (REV. 4/98)	Page						

Competing Continuation Applications PERSONNEL REPORT

All Personnel for the Current Budget Period

Name	Degree(s)	SSN	Role on Project (e.g. PI, Res. Assoc.)	Date of Birth (MM/DD/YY)	Annual % Effort
Galilei, Galileo	BS, MD	123-45-6789	Principal Investigator	03/03/38	40
Copernicus, Nicholas	BS, PhD		Research Assistant	04/04/58	25
Newton, Isaac	BS, MS, PhD		Staff Scientist	05/05/53	50
PHS 398 (REV. 4/98)		Page			JJ

Place this form at the end of the signed original copy of the application. Do <u>not</u> duplicate.

Scial Security No. 123-45-6789

PERSONAL DATA ON PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR

The Public Health Service has a continuing commitment to monitor the operation of its review and award processes to detect—and deal appropriately with—any instances of real or apparent inequities with respect to age, sex, race, or ethnicity of the proposed principal investigator/program director.

To provide the PHS with the information it needs for this important task, complete the form below and attach it to the signed original of the application after the Checklist. **Do not attach copies of this form to the duplicated copies of the application.**

Upon receipt of the application by the PHS, this form will be separated from the application. This form will **not** be duplicated, and it will **not** be a part of the review process. Data will be confidential, and will be maintained in Privacy Act record system 09-25-0036, "Grants: IMPAC (Grant/Contract Information)." All analyses conducted on the data will report aggregate statistical findings only and will not identify individuals.

If you decline to provide this information, it will in no way affect consideration of your application.

Your cooperation will be appreciated.

DATE OF BIRTH (MM/DD/YY)		GENDER						
	03/03/38	Female	Male					
RACE AND/OR ETHNIC ORIGIN (check one)								
Note: The category that most closely reflects the individual's recognition in the community should be used when reporting mixed racial and/or ethnic origins.								
	American Indian or Alaskan Native. A person having origins in any of the original peoples of North America, and who maintains a cultural identification through tribal affiliation or community recognition							
	Asian or Pacific Islander. A person having origins in any of the original peoples of the Far East, Southeast Asia, the Indian subcontinent, or the Pacific Islands. This area includes, for example, China, India, Japan, Korea, the Philippine Islands, and Samoa.							
	Black, not of Hispanic origin. A person having origins in any of the black racial groups of Africa.							
	Hispanic. A person of Mexican, Puerto Rican, Cuban, Central or South American, or other Spanish culture or origin.							
	White, not of Hispanic origin. A person having origins in East.	n any of the origi	nal peoples of Europe, North Africa, or the Middle					
\bigvee	Check here if you do not wish to provide some or all of the	above information	า					

Inclusion Report Format For Each Study

Initially: Provide the number of subjects proposed for the study according to the following categories. If there is more than one study, provide a separate table for each study. In addition, report on the sub-populations that are proposed to be included in the study.

Annually: Provide the number of subjects enrolled in the study to date, according to the following categories. If there is more than one study, provide a separate table for each study. In addition, report on the subpopulations that are proposed to be included in the study.

Gender and Minority Inclusion

Study Title: This is where the Gender and Minority Inclusion Study Title goes.

	American Indian or Alaskan Native	Asian or Pacific Islander	Black, not of Hispanic Origin	Hispanic	White, not of Hispanic Origin	Other or Unknown	Total
Female	50	50	50	50	50	100	350
Male	35	35	35	35	35	70	245
Unknown							
Total	85	85	85	85	85	170	595

Below is the HTML-stream that corresponds to the sample form. Although an HTML-stream is a continuous sequence of characters, new lines and tabs have been inserted for readability.

```
BEGIN=APPLICATION
 &Purpose=00
 &Type=6C
 &Applicant Id=UniversityGrantID01
 &Submission Date=19970602
 &Title=Atherosclerosis+Prevention+Study
 &Award Id=5R01AI0000001A1
 &BEGIN=ORGANIZATION
   &Type=SE
   &DUNS=112233445
   &Profile_Id=1234567
   &Name=University+of+Bethesda
   &EIN=0123454321A1
   &Entity_Type=A8
   &BEGIN=ICR
     &Agree Date=19980101
   &END=ICR
   &BEGIN=CONTACT INFORMATION
     &Street_Address=461+Ocean+Blvd.
     &City=Bethesda
     &State=MD
     &Zip Code=20892
   &END=CONTACT INFORMATION
 &NEXT=ORGANIZATION
   &Type=BY
   &DUNS=927645168
 &END=ORGANIZATION
 &BEGIN=INDIVIDUAL
   &Type=AD
   &Last Name=Brahe
   &First Name=Tycho
   &Middle Name=H.
   &Title=Deputy+Director
   &BEGIN=CONTACT_INFORMATION
     &Street_Address=Department+of+Contracts+and+Grants
     &Street_Address=1313+Mockingbird+Lane,+DEI-5555
     &City=Bethesda
     &State=MD
     &Zip Code=20892
     &Email Address=tbrahe@munster.ub.edu
     &Telephone_Number=3015552396
     &Fax Number=3015552835
   &END=CONTACT_INFORMATION
 &NEXT=INDIVIDUAL
   &Type=1B
   &Last_Name=Bruno
```

```
&First Name=Giordano
 &Suffix=Jr.
 &Title=Provost+&+Senor+VP+for+Academic+Affairs
 &BEGIN=CONTACT_INFORMATION
   &Street_Address=Department+of+Contracts+and+Grants
   &Street_Address=1313+Mockingbird+Lane,+DEI-5555
   &City=Bethesda
   &State=MD
   &Zip_Code=20892
   &Email Address=giordano.bruno@ub.edu
   &Telephone Number=3015552390
   &Fax Number=3015554414
 &END=CONTACT_INFORMATION
&NEXT=INDIVIDUAL
 &Type=AZ
 &Last_Name=Schmidt
 &First Name=Berhard
&END=INDIVIDUAL
&BEGIN=YES NO CONDITION
 &Type=J.1
 &Response=Y
&END=YES NO CONDITION
&BEGIN=PROJECT
 &Type=PC
 &Start Date=19980401
 &End Date=20000331
 &Duration=24
 &BEGIN=ORGANIZATION
   &Type=61
   &Name=
                 Pharmacology+Research+Laboratory
   &BEGIN=CONTACT INFORMATION
     &City=Bethesda
     &State=MD
     &Country=US
   &END=CONTACT INFORMATION
 &END=ORGANIZATION
 &BEGIN=PARAGRAPH
   &Type=A
   &Text=This+is+where+the+abstract+would+go.
 &NEXT=PARAGRAPH
   &Type=B.2
   &Text=This+is+where+the+specific+aims+would+go.
 &NEXT=PARAGRAPH
   &Type=C.2
   &Text=Laboratory:+These+studies+will+be+
    performed+in+the+laboratory+of+Dr.+Galilei.
     ++Dr.+Galilei's+laboratory+is+located+in+
     the+Clinical+Research+Center+of+the+
     University+of+Bethesda.++The+laboratory+
     contains+sinks,+benches,+refrigerators,+and+
```

```
freezers+for+in+vitro+studies.++Clinical:+
   There+is+full+access+to+patients+at+the+
   Pharmacology+Research+Laboratory+in+
   Bethesda, +MD. ++In+addition, +there+is+
   support+of+community+physicians.++Animal:+
   There+are+animal+housing+and+procedure+
   rooms+in+the+Clinical+Research+Center.++
   This+facility+is+staffed+by+veterinarians+
   and+animal+husbandry+personnel.++Computer:+
   Dr.+Galilei's+laboratory+contains+a+network+
   of+Pentium+PCs+with+two+color+laser+
   printers.++The+network+has+direct+access+to+
   the+Internet+via+the+University+of+Bethesda+
   backbone.++Office:+There+are+several+
   offices+adjacent+to+Dr.+Galilei's+
   laboratory+with+desks,+bookshelves,+filing+
   cabinets+and+computer+systems.++These+can+
   be+used+by+both+investigators+and+
   administrative+personnel.
&NEXT=PARAGRAPH
 &Type=C.3
 &Text=The+Clinical+Research+Center+contains+
   the+following:+Liquid+scintillation+
   counter, +ultracentrifuge, +refrigerated+
   centrifuge, +C02+incubator, +radioisotope+
   detector, +microscopes, +balances, +and+a+
   digital+imaging+system+with+computer+
   control+and+perfusion+equipment.
&NEXT=PARAGRAPH
 &Type=I.6
 &Text=REPORTED
&NEXT=PARAGRAPH
 &Type=E.4
 &Text=For+budget+period+04/01/98-
 03/31/99,+receive+an+anticipated+
 amount+of+$50,000+from+Howard+Hughes
 +Medical+Institute
&END=PARAGRAPH
&BEGIN=ANIMAL_SUBJECT
 &BEGIN=IACUC
   &Assurance_Number=A999901
   &Approval Date=19970201
 &END=IACUC
&END=ANIMAL SUBJECT
&BEGIN=HUMAN SUBJECT
 &BEGIN=IRB
   &Assurance_Number=M123456XB
   &Approval_Pending=Y
 &END=IRB
 &BEGIN=MATRIX
```

```
&Title= This+is+where+the+Gender+and
     +Minority+Inclusion+Study+Title+goes.
   &Start_Cell=A1
   &End Cell=F2
   &Data=50
   &Data=50
   &Data=50
   &Data=50
   &Data=50
   &Data=100
   &Data=35
   &Data=35
   &Data=35
   &Data=35
   &Data=35
   &Data=70
 &END=MATRIX
&END=HUMAN_SUBJECT
&BEGIN=INDIVIDUAL
 &Type=9P
 &Last_Name=Galilei
 &First_Name=Galileo
 &Middle_Name=N.
 &Title=Professor+of+Medicine
 &SSN=123456789
 &Birth Date=19380303
 &Sex=M
 &BEGIN=RACE ETHNICITY
   &Type=7
 &END=RACE_ETHNICITY
 &BEGIN=CONTACT_INFORMATION
   &Street_Address=Atherosclerosis+Research+Unit
   &Street_Address=461+Ocean+Blvd.,+MSC-32
   &City=Bethesda
   &State=MD
   &Zip_Code=20892
   &Email Address=ggalilei@ub.edu
   &Telephone_Number=3015551478
   &Fax_Number=3015552685
 &END=CONTACT_INFORMATION
 &BEGIN=ORGANIZATION
   &Type=9P
   &Name=University+of+Bethesda
   &DUNS=112233445
   &Department=MDK
   &Division=01
 &END=ORGANIZATION
 &BEGIN=EDUCATION
   &Type=BS
   &Date=195905
```

```
&Institution=University+of+Northern+Italy
 &Major=Medicinal+Chemistry
&NEXT=EDUCATION
 &Type=MD
 &Date=196312
 &Institution=University+of+Pisa
 &Major=Medicine
&END=EDUCATION
&BEGIN=PARAGRAPH
 &Type=D.1
 &Text=1963-1965:+University+of+California,+
   Los+Angeles.++Department:+Medicine.+
   Resident.
&NEXT=PARAGRAPH
 &Type=D.1
 &Text=1965-1974:+University+of+California,+
   Los+Angeles.++Department:+Medicine.+
   Medical+Resident.
&NEXT=PARAGRAPH
 &Type=D.1
 &Text=1974-1979:+University+of+California,+
   Los+Angeles.++Department:+Medicine.+
   Chief+Resident.
&NEXT=PARAGRAPH
 &Type=D.1
 &Text=1979-1992:+University+of+California,+
   San+Diego.++Department:+Medicine.+
   Associate+Professor+of+Medicine.
&NEXT=PARAGRAPH
 &Type=D.1
 &Text=1992-1997:+University+of+Bethesda.++
   Department: +Medicine. +Professor+
   of + Medicine.
&NEXT=PARAGRAPH
 &Type=D.3
 &Text=Years:+1994-1995+JM+Osbourne+
   Preventive+Medicine+Award
&NEXT=PARAGRAPH
 &Type=D.3
 &Text=Years:+1995-1996+American+Society+
   for+Immunology+Travel+Award
&NEXT=PARAGRAPH
 &Type=D.4
 &Text=Federal+Advisory+Committee+
   Membership.+Agency:+NIDDK+Title:+GMA-2+
   Study+Section+Start+Year:+01/01/93+
   End+Year:+01/01/1997
&NEXT=PARAGRAPH
 &Type=D.5
 &Text=Galilei,+G.,+Brown+C+(1997).+The+
```

```
pathogenesis+of+coronary+disease.+
   New+England+Journal+of+Medicine,
   +236:+142-150.
&NEXT=PARAGRAPH
 &Type=D.5
 &Text=Galilei,+G.,+Robin,+C.+(1995).
   +Triggering+of+plague+disruption.+
   Circulation, ++81:+576-584.
&NEXT=PARAGRAPH
 &Type=D.5
 &Text=Galilei,+G.,+Dilbert+D.+(1995)+
   Arterial+imaging+and+atherosclerosis+
   reversal.++Arterioscler+Thromb.+14:
   +77 - 92.
&END=PARAGRAPH
&BEGIN=OTHER SUPPORT
 &Type=37
 &Title=Chloride+and+Sodium+Transport
   in+Airway+Epithelial+Cells
 &Annual Cost=186529
 &Award Number=2R01HL0000013
 &Major Goals=
                         The+major+goals+of+this+
   project+are+to+define+the+
   biochemistry+of+chloride+and+sodium+
   transport+in+airway+epithelial+cells+
   and+clone+the+gene(s)+involved+in+
   transport.
 &BEGIN=OTHER SUPPORT PERIOD
   &Start Date=19960301
   &End_Date=19990228
   &Level Effort Percentage=30
 &END=OTHER_SUPPORT_PERIOD
 &BEGIN=ORGANIZATION
   &Type=92
   &Name=NIH/NHLBI
 &END=ORGANIZATION
 &BEGIN=INDIVIDUAL
   &Type=9P
   &Last_Name=Galilei
   &First_Name=Galileo
 &END=INDIVIDUAL
&NEXT=OTHER SUPPORT
 &Type=A3
 &Title=Liposome+Membrane+Composition+
   and+Function
 &Annual Cost=82163
 &Award_Number=DCB950000
                         The+major+goals+of+this+
 &Major_Goals=
   project+are+to+define+biochemical+
   properties+of+liposome+membrane+
```

```
components+and+maximize+liposome+
     uptake+into+cells.
   &Overlap=There+is+scientific+overlap
     +between+aim+2+of+NSF+DCB+950000
     +and+aim+4+of+the+application+
     under+consideration.++If+both+are+
     funded, +the+budgets+will+be+adjusted+
     appropriately+in+conjunction+with+
     agency+staff.
   &BEGIN=OTHER SUPPORT PERIOD
     &Start Date=19981201
     &End_Date=20001130
     &Level_Effort_Percentage=20
   &END=OTHER SUPPORT PERIOD
   &BEGIN=ORGANIZATION
     &Type=92
     &Name=National+Science+Foundation
   &END=ORGANIZATION
   &BEGIN=INDIVIDUAL
     &Type=9P
     &Last_Name=Galilei
     &First Name=Galileo
   &END=INDIVIDUAL
 &END=OTHER_SUPPORT
&NEXT=INDIVIDUAL
 &Type=9K
 &Last_Name=Copernicus
 &First Name=Nicholas
 &Title=Clinical+Investigator
 &Birth_Date=19580404
 &BEGIN=ORGANIZATION
   &Type=9K
   &Name=University+of+Bethesda
   &DUNS=112233445
 &END=ORGANIZATION
 &BEGIN=EDUCATION
   &Type=BS
   &Date=197905
   &Institution=University+of+Cracow
   &Major=Biological+Chemistry
 &NEXT=EDUCATION
   &Type=PHD
   &Date=198312
   &Institution=University+of+Cracow
   &Major=Biological+Chemistry
 &END=EDUCATION
 &BEGIN=PARAGRAPH
   &Type=D.1
   &Text=1983-1986:+National+Institute+of+
     Allergy/Infectious+Disease.+
```

```
+Department:+Lab+of+Clinical+
     Investigation.+Visiting+Fellow.
 &NEXT=PARAGRAPH
   &Type=D.1
   &Text=1986-1992:+University+of+
     Bethesda.++Department:+Medicine.+
    Medical+Resident.
 &NEXT=PARAGRAPH
   &Type=D.1
   &Text=1992-1997:+
     University+of+Bethesda.++Department:+
    Medicine.+Clinical+Investigator.
 &NEXT=PARAGRAPH
   &Type=D.4
   &Text=Agency:+DRG+NIH.+Title:+Ad+hoc+
     reviewer++GMA-2+Study+Section.+
     Start+year:+01/01/96
 &NEXT=PARAGRAPH
   &Type=D.5
   &Text=Copernicus, +N., +Pooh+W.+(1997)+
     Risk+factor+assessment+and+prevention
     +of+coronary+artery+disease.+J+Intern
     +Med.;263:211-3.
 &NEXT=PARAGRAPH
   &Type=D.5
   &Text=Copernicus, +N., +McDonald+R.+(1997)+
     Cholesterol+Lowering+Atherosclerosis
     +Study+(CLAS).+Controlled+Clin+Trials.
     +18:156-87.
 &END=PARAGRAPH
&NEXT=INDIVIDUAL
 &Type=9K
 &Last_Name=Newton
 &First Name=Isaac
 &Title=Biostatician
 &Birth Date=19530505
 &BEGIN=ORGANIZATION
   &Type=9K
   &Name=University+of+Bethesda
   &DUNS=112233445
 &END=ORGANIZATION
 &BEGIN=EDUCATION
   &Type=BS
   &Date=197505
   &Institution=New+University+College,+London
   &Major=Mathematics
 &NEXT=EDUCATION
   &Type=MS
   &Date=197806
   &Institution=New+University+College,+London
```

```
&Major=Mathematics
&NEXT=EDUCATION
 &Type=PHD
 &Date=198212
 &Institution=Cambridge+University
 &Major=Biometry
&END=EDUCATION
&BEGIN=PARAGRAPH
 &Type=D.1
 &Text=1982-1984:+Jackson+Memorial+Hospital,+
   +Department: +Medicine. +Staff+Research+
   Associate.
&NEXT=PARAGRAPH
 &Type=D.1
 &Text=1984-1988:+University+of+Illinois,
   +Medical+School.++Department:+Medicine.
   +Associate+Specialist.
&NEXT=PARAGRAPH
 &Type=D.1
 &Text=1988-1997:+University+of+Bethesda.++
   Department: +Medicine. +Associate+
   Professor+of+Biometry.
&NEXT=PARAGRAPH
 &Type=D.5
 &Text=Newton, +I., +Greenjeans, +M.+
   (1996)+Effects+of+colestipol-niacin+
   therapy+on+atherosclerosis.+Circulation.+
   38:138-47.
&END=PARAGRAPH
&BEGIN=OTHER_SUPPORT
 &Type=37
 &Title=Gene+Cloning+and+Targeting+for+
   +Neurological+Disease+Genes
 &Annual Cost=581317
 &Award_Number=Investigator+Award
 &Major_Goals=
                         This+award+supports+the+
   PI's+program+to+map+and+clone+the+
   gene(s)+implicated+in+the+
   development+of+Alzheimer's+disease
   +and+to+target+expression+of+the+
   cloned+gene(s)+to+relevant+cells.
 &BEGIN=OTHER SUPPORT PERIOD
   &Start Date=19970901
   &End Date=20010831
   &Level_Effort_Percentage=70
 &END=OTHER_SUPPORT_PERIOD
 &BEGIN=ORGANIZATION
   &Type=92
   &Name=Howard+Hughes+Medical+Institute
 &END=ORGANIZATION
```

```
&BEGIN=INDIVIDUAL
     &Type=9P
     &Last_Name=Newton
     &First Name=Isaac
   &END=INDIVIDUAL
 &END=OTHER_SUPPORT
&END=INDIVIDUAL
&BEGIN=BUDGET
 &BEGIN=PARAGRAPH
   &Type=C.1
   &Text=This+is+where+the+budget+
     justification+would+go.
 &END=PARAGRAPH
 &BEGIN=BUDGET PERIOD
   &Period_Id=T
   &Start_Date=19980401
   &Length=24
   &BEGIN=BUDGET_ITEM
     &Code=84
     &Cost=1098404
   &NEXT=BUDGET_ITEM
     &Code=38
     &Cost=1664082
   &NEXT=BUDGET_ITEM
     &Code=47
     &Quantity=1098404
     &Percentage_Rate=51.50
     &Cost=565678
   &END=BUDGET_ITEM
 &NEXT=BUDGET_PERIOD
   &Period_Id=1
   &Start_Date=19980401
   &Length=12
   &BEGIN=BUDGET_LABOR
     &Project Role=Principal+Investigator
     &Level_Effort_Months=12
     &Level Effort Percentage=40
     &Previous_Level_Effort_Percentage=40
     &Salary=110000
     &Requested_Salary=44000
     &Requested_Benefits=13772
     &BEGIN=INDIVIDUAL
      &Type=9P
      &Last Name=Galilei
      &First_Name=Galileo
      &Middle Name=N.
     &END=INDIVIDUAL
   &NEXT=BUDGET_LABOR
     &Project_Role=Research+Assistant
     &Level_Effort_Months=11
```

```
&Level Effort Percentage=32
 &Previous_Level_Effort_Percentage=25
 &Salary=119719
 &Requested_Salary=38574
 &Requested_Benefits=12073
 &BEGIN=INDIVIDUAL
   &Type=9K
   &Last Name=Copernicus
   &First Name=Nicholas
 &END=INDIVIDUAL
&NEXT=BUDGET_LABOR
 &Project_Role=Staff+Scientist
 &Level_Effort_Months=12
 &Level_Effort_Percentage=10
 &Previous_Level_Effort_Percentage=50
 &Salary=125000
 &Requested_Salary=0
 &Requested_Benefits=0
 &BEGIN=INDIVIDUAL
   &Type=9K
   &Last_Name=Newton
   &First_Name=Isaac
 &END=INDIVIDUAL
&NEXT=BUDGET_LABOR
 &Project Role=Supportee
 &Level_Effort_Months=12
 &Level_Effort_Percentage=50
 &Salary=25331
 &Requested_Salary=12666
 &Requested_Benefits=3964
 &BEGIN=INDIVIDUAL
   &Type=EY
   &Last_Name=Keplar
   &First Name=Johannes
 &END=INDIVIDUAL
&NEXT=BUDGET LABOR
 &Labor Category=Supportee
 &Level_Effort_Months=12
 &Level_Effort_Percentage=100
 &Salary=35000
 &Requested_Salary=35000
 &Requested_Benefits=10955
&NEXT=BUDGET LABOR
 &Labor Category=Lab+Technician
 &Level_Effort_Months=12
 &Level_Effort_Percentage=100
 &Salary=32000
 &Requested_Salary=32000
 &Requested_Benefits=9600
&NEXT=BUDGET_LABOR
```

```
&Labor Category=Lab+Technician
 &Level_Effort_Months=12
 &Level_Effort_Percentage=100
 &Salary=36000
 &Requested_Salary=36000
 &Requested_Benefits=10800
&END=BUDGET LABOR
&BEGIN=BUDGET ITEM
 &Code=84
 &Cost=470757
&NEXT=BUDGET ITEM
 &Code=38
 &Cost=713196
&NEXT=BUDGET ITEM
 &Code=47
 &Quantity=470757
 &Percentage_Rate=51.50
 &Cost=242439
&NEXT=BUDGET ITEM
 &Code=81
 &Cost=22400
&NEXT=BUDGET ITEM
 &Code=42
 &Cost=5500
 &Description=Single+cell+Perfusion+
   Chambers+and+Filter+Sets
&NEXT=BUDGET ITEM
 \&Code=42
 &Cost=15000
 &Description=Centrifuge
&NEXT=BUDGET_ITEM
 &Code=72
 &Cost=20500
&NEXT=BUDGET ITEM
 &Code=43
 &Cost=5400
 &Description=Office, +postage, +and+
   xerographical+supplies+for+Clinic,
   +Biostatisical, +and+Administrative
   +components+$4000.++Lipid+Laboratory
   +supplies+$1400.
&NEXT=BUDGET ITEM
 &Code=52
 &Cost=4000
 &Description=Travel+to+National+
   meetings+for+3+individuals
&NEXT=BUDGET_ITEM
 &Code=85
 &Cost=3500
&NEXT=BUDGET ITEM
```

```
&Code=BL
        &Cost=84720
      &NEXT=BUDGET_ITEM
        &Code=87
        &Cost=28750
      &NEXT=BUDGET_ITEM
        &Code=EH
        &Cost=1183
       &NEXT=BUDGET_ITEM
        &Code=80
        &Cost=1500
      &NEXT=BUDGET_ITEM
        &Code=86
        &Cost=4400
      &NEXT=BUDGET_ITEM
        &Code=39
        &Cost=35000
       &END=BUDGET_ITEM
     &NEXT=BUDGET PERIOD
      &Period Id=2
      &Start_Date=19990401
      &Length=12
      &BEGIN=BUDGET_ITEM
        &Code=84
        &Cost=627647
      &NEXT=BUDGET ITEM
        &Code=71
        &Cost=465898
      &NEXT=BUDGET_ITEM
        &Code=81
        &Cost=23296
      &NEXT=BUDGET_ITEM
        &Code=43
        &Cost=5616
      &NEXT=BUDGET ITEM
        &Code=52
        &Cost=4098
      &NEXT=BUDGET_ITEM
        &Code=BL
        &Cost=87648
      &NEXT=BUDGET_ITEM
        &Code=39
        &Cost=41091
      &END=BUDGET ITEM
     &END=BUDGET_PERIOD
   &END=BUDGET
 &END=PROJECT
&END=APPLICATION
```